

**Percutaneous Coronary Intervention Advisory Oversight Committee
Meeting
January 17, 2013, Sacramento, California
09:30 a.m. to 2:30 p.m.**

Attendance

Members Anthony Way, MD, Chair; French, William, M.D.; George Fehrenbacher, MD; Steven Forman, MD; Aditya Jain, MD; Sushil Karmarkar, MD; Ralph Brindis, M.D; Rohit Sundrani, MD, Robert Davidson, M.D.; Steven Arnold, M.D.;

UC Davis Tanuj Patel, MBBS; William Bommer, MD; Zhongmin Li, PhD; Geeta Mahendra, MS; Suresh Ram, MBBS; Laurie Vazquez, ANP

Facilitators Teresa Fleege; Sheila Fleege

Agenda Items/Discussion	Action/ Follow-up
<p>09:34 Call to Order and Introductions: PCI AOC Chair Anthony Way (Chair) convened the meeting with introductions in the room and on the conference line.</p> <p>Approval of Minutes:</p> <ul style="list-style-type: none"> • No Changes <p>Motion to approve October 4, 2012 as written</p> <ul style="list-style-type: none"> ➤ Motion— Fehrenbacher ➤ Second—Karmarkar ➤ Motion passed as written by unanimous vote <p>Public Comment</p> <ul style="list-style-type: none"> • None 	
<p>Dr. Fehrenbacher – I think we discussed this at two meetings already so I do not need to go through slides and the whole matter again. I will make a motion that the AOC endorses the language of SB 891 that the IRB approval of the consent form is no longer mandated but it is left up to the individual hospital.</p> <p>Dr. Way – Does everybody understand the motion?</p> <p>Dr. Brindis – Can we have a discussion and do we need a second?</p> <p>Dr. Way – Thank you for keeping me legitimate.</p> <p>Dr. Arnold – I will second.</p>	

<p>Dr. Way – We have a second from Dr. Arnold.</p> <p>Dr. Ralph Brindis – I have a question for Bill Bommer. Does this influence at all in terms of the ability to continue this study in the manner that you would want with the possibility that the IRB approvals will be more at the discretion of the hospital and the practicing physician?</p> <p>Dr. Bommer – As far as the coordinating center is concerned, we will continue with our IRB approval for the coordinating center. The reason being we are collecting data, although not technically a research project, it does incorporate the collection of information that is patient-specific information that is done both in the audits and in the registry. We feel that it is much more compliant to continue with IRB from our local IRB for our process which is the collection of data. As far as the individual pilot site hospitals, it is basically up to IRB at the local pilot hospital as to whether they feel they would need continuing IRB approval or not. The only thing that we would request is that (1) this change not alter the capability of referring the patient's information directly to the registry which is being used for this and (2) that whatever consent the patient signs they acknowledge the fact that in the state of California this is a trial program under Senate Bill 891 because it currently does not match the Title 22 requirements for PCI in the state of California.</p> <p>Dr. Brindis – So at an individual hospital they will have to make the decision that you describe of relinquishing the need for an IRB. They would need to have something in a consent form to acknowledge to the patient that this is a study. Is there any HIPAA compliant issue related to patient data coming over if they do not sign an IRB form?</p> <p>Dr. Bommer – I believe that the consent form that a patient signs at a hospital . . . The hospital has agreed to be in this program . . . The consent process would have to acknowledge that the patient's data would be transferred to a central coordinating center for evaluation.</p> <p>Dr. Brindis – So that would imply that if a hospital wanted to do that – I am just thinking about what Kaiser Permanente would do –They would actually have to come up with a consent form that is different than the standard consent form, let's say a hospital would use, and have to go through their committee structure to have that approved? Am I thinking on base or off base?</p> <p>Dr. Bommer – Well the consent for PCI at an individual site hospital would have to include language that the personal or medical data from this procedure will be forwarded to a central coordinating center for review and possible audit.</p> <p>Dr. Brindis – So listening to what you have to say makes me, as a member of the AOC Committee, want to have a rider to the motion of George that our committee would say that if the hospital decides to forego an IRB they have a consent form that would meet the needs of being able to collect the data in the manner in which you described. That is the thought that I would have.</p> <p>Dr. Arnold – The patients are already signing a second medical release form for you to get the data primarily for those patients that are not part of the elective but come in as an emergency angioplasty. They obviously are not signing the consent form from the CAMPOS. They are signing the standard hospital consent but then they are signing a second consent in order to release the data to you anyway?</p> <p>Dr. Fehrenbacher – In our situation we have a PCI consent for those patients who, for whatever reason, cannot sign the 12-page consent form (usually it is some sort of emergency) that the data is released to both CDPH and UC Davis. That is already in our consent form. There is essentially one consent form. Are you suggesting that you need more than that? What language exactly are you suggesting? One of the issues here I think is that whether this is research or not, and whether this is a quality improvement project on hand, then we collect it all the time on patients for everything we do in the hospital for quality improvement. On one end of the spectrum vs. the</p>	
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<p>other end of the spectrum is a procedure or device that has not been approved by the FDA and that is clearly reasoned. So the question is where this lies in that spectrum in that continuum. Data is being collected and once the ACC-AHA deemed it no longer class 3 – that it is an acceptable thing to do – then I would submit that it is no longer experimental.</p> <p>Dr. Brindis – I agree 1,000% with what your comments are. Again, as you pointed out relating to the gist of the Bill originally an IRB was not required. On the other hand, the due diligence that I feel as a member of this committee in supporting the state in its pilot project, in terms of being able to offer the legislature information so they may make the decision that you would find in your hospital that would find advantageous – that is, to change the paradigm for elective PCI – I think, requires us to collect the data on those patients. That is why I agree totally with what you say, but I am interested from a state perspective in being able to offer the legislature the data necessary for them through the analytical center of Bill Bommer to make the informed decision that I am sure you would like to have.</p> <p>Dr. Fehrenbacher – I agree with you 100%. I think we should collect the data. I think we are both on the same page. The question is – does it need to be in the 12-page consent form that we currently have that is extremely conservative.</p> <p>Dr. Brindis – I am okay with letting that go. Right now my interpretation is if you just have a standard generic consent form it will not necessarily meet the needs of the AOC in being able to be HIPAA compliant in the data being submitted to the analytical center, and I want to ensure that.</p> <p>Dr. Fehrenbacher – So if you would like to add an amendment to the motion such that the data can be collected and submitted to CDPH and UC Davis I am fine with that.</p> <p>Dr. French – I do not understand why more than half way through this process we want to change the rules. It is still a research project no matter what you think it is.</p> <p>Dr. Way – The wording of the senate bill allows the removal of the IRB if the cardiology groups state that it is no longer an experimental procedure. That is the only thing we are talking about.</p> <p>Dr. French – But it is an experimental study to see if this is a way to go in the future.</p> <p>Dr. Way – I am just speaking to the way that the senate bill was written. We had legal counsel say that if it meets the standard you do not have to do it. If you want to do it for other reasons that is of course your prerogative.</p> <p>Dr. French – Then why are we still meeting as a group?</p> <p>Dr. Way – We are still meeting as a group because we have to report to the legislature at the end of the three-year pilot project so they can move forward.</p> <p>Dr. French – They have already concluded that it is no longer necessary.</p> <p>Dr. Way – That is not my understanding of the charge that this committee has.</p> <p>Dr. Fehrenbacher – I would argue that the recent randomized trials have allowed the American Heart Association and ACC Committee to state that it is no longer a class-3 indication and that it is acceptable to do. On one hand, it is therefore no longer experimental but on the other hand we are left with a 1982 relic of a bill.</p> <p>Dr. Way – It is a regulation. Regulations have to be changed. It is still not going to be allowed even if the IRB is not required, except within this pilot program, in a hospital you cannot do interventional cardiology in a hospital that does not have in-house cardiac surgery.</p>	
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Dr. French – That would support the idea that we should not be changing what the local IRB can do. We have to live with the regulations we have now.

Dr. Way – But the reason, as Bill said, as long as the ACC-AHA guidelines categorize elective PCI with offsite surgery as class-3 indication then the IRB needs to approve the form, but the law says that once it is no longer that way then it is no longer required.

Dr. French – Is that the current law?

Dr. Way – Yes, that is the current law.

Dr. Karmarkar – My concern is that as long as the study is not jeopardized in any way in terms of patient data collection and transmittal of patient specific information PHI that is HIPAA compliant. That is part of the consent process. We can have a truncated version of the consent process left up to the individual hospital. The three elements are (1) part of the pilot program, (2) patient is aware that your data is being released in a HIPAA compliant way to the CDPH and UC Davis, and (3) that you are actually consenting for the procedure. As long as these three elements are included in the consent process I am okay with altering the form and making it a abridged version of the form.

Dr. Way – I accept that as an amendment.

Dr. Jain – Then shouldn't we assure that all hospitals are doing the same thing?

Dr. Way – What do you mean by all hospitals?

Dr. French – Well if one IRB can say yes and the other says no then they are not all following the same rules.

Dr. Way – The original motion was that it is up to the hospital to decide if they want to continue IRB or not.

Dr. French - But does that make sense? It just seems that you are either part of the process or you're not part of the process. Having individual hospitals decide that they are going to go one way and another hospital is going to go another way it doesn't seem to make a lot of sense.

Dr. Brindis – Bill, I acknowledge your comment. I have been involved in a work through the NCDR where we appreciate that some centers require IRBs and some don't, and we have been able to work around that appreciating that not everybody has that same local oversight intensity.

Dr. French – I get that. I am very familiar with that, but the issue here is this is a very special and unique study in the State of California to try and change the outdated regulation. Usually when you do things like that it is a study and you are all doing the same thing. If they have different IRBs then there are going to be different types of documents, and it would seem like you would participate in the same process. I don't know why we would want to change. How much longer is this study going to take, another year?

Dr. Brindis – That is an item for later discussion.

Dr. French – It just seems like we are more towards the 10th hour than the beginning and to change at this time just seems to be not what is needed.

Dr. Brindis – One argument you could make is to continue the IRB to the end of the year and then extend the study in the manner that Dr. Bommer may propose without the IRB requirement depending on the individual hospital choice. That could be an additional rider that you could

<p>offer.</p> <p>Dr. French – I think that would make a lot more sense.</p> <p>Dr. Way – We have the original proposal with the first addendum. The second addendum removes the whole process. I think we need to have a vote. Dr. Fehrenbacher could you restate the motion with the addendum you accepted?</p> <p>Dr. Fehrenbacher – That the AOC endorses the language of SB 891, that the IRB approval of the consent form is no longer mandated, but it is left up to the individual hospital as long as the consent form allows data to be submitted to both CDPH and UC Davis in a HIPAA compliant fashion.</p> <p>Dr. Way – Let's have a call for vote. I am going to read the names, Dr. Fehrenbacher (yes), Dr. Jain (no), Dr. Karmarkar (yes), Dr. Arnold (yes), Dr. Forman (yes), Dr. Brindis (yes), Dr. French (no). Are there any other members that I have not called on, that are here today? No answer. We have five yes's and two no's, so it passes.</p> <p>Dr. Brindis – Is that a quorum for this meeting? Is it a majority of the committee or a majority present?</p> <p>Dr. Way – We have a quorum and we have to go with a majority of the quorum so it passes. We are through with this so if somebody wants to make another final comment that is fine.</p> <p>Dr. Brindis – Again, I am concerned in the duty I have for the state is to have assurance for the UC Davis Analytical Center that they actually are able to get the data required. I am hopeful that as we have this discussion with the individual centers that it become clear that they either need to continue the IRB process or figure out a consent form where all the information necessary to continue this study can be obtained by the state.</p> <p>Erica Marmolejo – I work closely with Dr. Karmarkar in the IRB and our submissions. I brought this topic up in discussion with our IRB administrator which is this still trying to answer a research question and what are the purposes ultimately is sending the data to UCC Davis? If it is under the auspice of the research question then we are not able to use our Kaiser standard disclosure of medical information because it specifically indicates "not for research." Unless there is going to be a language from UC Davis or the state that is going to say specifically outright that this is not going to support a research venture, or add to general knowledge, our institution probably will continue with our informed consent form the way it is through the IRB.</p> <p>Dr. Way – That is part of the issue that was just brought and voted on – that you are welcome to continue with your IRB consent form. It makes it elective.</p> <p>Dr. French – So we shouldn't be putting this project in jeopardy at this hour if we are not sure that this is the case with other facilities. It seems to be that the timing is off here.</p> <p>Dr. Way – I don't have any comment to that. The statute was written. This loophole, if you will, was allowed, it has been voted on, and it's up to the individual facilities to decide what they want to do when they are taking a consent.</p> <p>Dr. French – But then we may not be able to collect the data?</p> <p>Dr. Brindis – If I understand the approved motion, if the hospital was not able to submit the data without using the IRB form they would still need to continue using the IRB.</p> <p>Dr. Way – It is entirely elective.</p>	
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Dr. Karmarkar – Yes, that’s my understanding. So as long as we are able to collect the data and the patients are aware that they are part of the study the consent form can be altered as long as it meets all the basic requirements of the SB 891.

Dr. French – I just don’t know why we want to put this in jeopardy. If this is going to happen then we wouldn’t be able to complete what we set out to do.

Dr. Way – I don’t see how it puts it in jeopardy. We are just voting on whether or not to use any IRB form. I think we need to go forward. Dr. Bommer, please proceed.

Dr. Bommer – Thank you very much, thank you everyone for joining us today. A quick comment on that last issue. For UC Davis we will continue with our IRB approval process for the coordinating center. The reason is logistics. It is a one-page sheet that we fill out once a year. It is easier to do that than to resubmit any new data, etc. I understand that it is more involved for the hospitals because of the consent form. I think that is basically the logistical reason that they are considering it at this time. We are going to move on to the “meat and potatoes” of the meeting which is the statistical analysis of the program and an update on the program since our last meeting that we held in the fall. I hope that everyone has access to the slides, the PowerPoint presentation that we sent out yesterday. For those of you in the room that do not have it I have handouts if you want to look at the slides or you can look at the screen. For those at the remote sites hopefully you have access to the slide set that you can bring up on your computer and I will try and coordinate it with you by listing the slide number that we are on at the time which is seen in the lower right hand corner of your slide. We will begin with slide number one which is the PCI Oversight Committee. This is not the cinema so we do not put our credits at the end of the movie. We put them at the beginning of the movie because we are never sure when the fire alarm will go off (laugh) so we want to at least acknowledge the efforts of the individuals. I counted up the number of people who I give credit to here, it is over some 75 people just to show you what you are involved with. The people here are involved in a truly large program to evaluate this problem for the State of California and make recommendations to them. At the coordinating center we have already announced all of these people who are here but we have a Statistical Analysis Team, a Technology Team, Velos Support Team, and NCDR Team. Joe Parker is here who helped us with early analysis from OSHPD and our Investigator Team that is here as well. That is on slide number two. On slide number three we look at the Pilot-Hospital Interventionalists. We believe that some or all of them may have been up all night last night taking care of STEMI patients, and we certainly acknowledge the fact that they contribute not only their daylight hours but many of their nighttime hours in participating in this study. Without them we could not in fact do this pilot program. On slide number four we acknowledge our coders who are at each hospital who sit there and relentlessly go through the data and actually read all of the notes and charts to code in 240 fields of data for every patient that has a PCI. They have pretty much by now learned the book of definitions and are able to be quite capable of handling those decisions. On slide number five we have the CDPH and AOC members who are gathered here today. We certainly want to acknowledge the fact that they are contributing their time. For the AOC members they do not get reimbursed for this. They are volunteering their time which is certainly needed to make those decisions. Now we will move on to slide number six. This is the total enrollment in the program as of December 31, 2012. On slide number six you can see in the bottom right hand corner that the total volume as of the end of the year was 3,076 patients so we have over 3,000 patients enrolled in the program. If we look at the population that we are serving you can see that the largest population of individuals in the program are STEMI patients. When this program was conceived one of the ideas was we need to get access to primary PCI for STEMI care out there and available. You can see the program is well serving that STEMI population with that being our largest group. You can see that we treat acute coronary syndromes. By definition that is STEMI, NSTEMI and unstable angina. You can see that they are the three largest groups in our total seen there. Almost one-third of our patients are STEMI patients in the 2-1/2 years that we have run the program so far. We are serving the population. We have achieved our minimum numbers with over 3,000 individuals enrolled in the PCI program. Slide number seven shows the enrollment per month. There is a cyclic variation

here. I leave it up to you to tell me what this correlates with. I have looked at different things and have not come out with that. Whoever guesses the cyclic relationship and what that correlates will get an extra sandwich at today's program. It goes up and down and I am not sure what it varies with but there are all kinds of proposals and theories that I have had. We are willing to evaluate any of those. You can see our overall enrollment per month is cyclic and goes up and down as it goes through. If we look at the individual hospitals and their variation in enrollment we look first at the top three volume hospitals. You can see the larger volume hospitals have enrolled anywhere from about 10 up to 40 patients per month for that. They also have a cyclic variation as we go through. These are hospitals number one, two and six in our protocol and those are the three larger volume hospitals in the pilot program. Slide number nine shows the lower volume hospitals in the program. You can also see a cyclic variation to that. You can see because they are the lower volume hospitals. Their numbers range anywhere from 2 to 28 patients per month. Those numbers are down from our higher volume hospitals for that. Slide number 10 shows our STEMI enrollment for years 1, 2 and 3. Year three is only 5 of 12 months of year three so it is literally just under half way through year three of the program. What you can see for STEMI enrollment is the hospitals have a varying proportion of patients who are STEMI. If we look at the top of the slide you can see our highest volume hospital at 162, 389 and 390 PCIs. Only less than 25% of their cases are STEMIs and that is hospital number one. However, if we look at another hospital, let's say hospital number six, we can see that really over half of those individuals at that hospital are STEMI patients. The STEMI population for individual hospitals varies anywhere from about 22% all the way up to about 55%. There is a variation even amongst the six pilot hospitals that we have here in their overall orientation. Despite that, the summation or the totals in STEMI is still our largest.

Dr. Way – Hello who just came on the phone?

Dr. Robert David – Hello, sorry I am late.

Dr. Way – Thanks for joining us.

Dr. Bommer – He is one of the AOC so our quorum just went up by one, thank you and welcome. Bob, I am on slide number nine on the slide set that was sent to you so hopefully you can access it.

Dr. Robert David – Thank you, have it.

Dr. Bommer – Now we are going to look at individual hospitals. So hospital number one, if you remember from the prior slide this was our largest volume hospital. They did 390 cases in the first year and 389 in the second year. It is about half of that for the third year so far and they have enrolled 941 patients. As we said earlier, about 22% of their patients are in fact STEMI. You can see for that hospital their biggest population is actually unstable angina in the total column at 254, followed by NSTEMI at 252, and then it drops back at that time to stable angina. This hospital's third component is actually stable angina in that situation followed by STEMI in that population. Moving to slide number 12 shows hospital number two. Again, hospital number two has STEMI as the predominant group seen here with acute coronary syndrome with the top rows being the highest number in that population base.

Dr. Forman – I apologize Bill, can you go back to hospital number one back to slide number 11. The notice that three patients had PCI with symptoms unlikely to be ischemic, was that determined by the hospital or by you?

Dr. Bommer – That is determined by the hospital. It is part of the NCDR code to check off the presentation at that point in time. If we were to audit that case we would confirm or verify that at the time. It is much more difficult to confirm that based on our data because that's entirely up to the history recorded at that time. We have no data to actually confirm it because we would have to call that patient by telephone to actually confirm it. Those numbers are relatively small as you

can see, but have been there in years 1, 2 and 3 in our other hospitals as well. Those situations could be someone who is getting a PCI because they are going to need a transplant surgery. Part of the requirement is they get an angio before they qualify, they see a lesion and the surgeon says, "I'm not going to do your kidney or liver transplant until someone fixes this." In that particular situation the patient could be absolutely asymptomatic and a surgeon says, "It's my preference to have you fixed before putting you on a list." Those are all individual cases and they are small numbers in our entire population. Slide number 12, we already discussed the fact that this hospital sees the largest group which is the STEMI population at 231. Hospital number three is shown on slide number 13. For hospital number three, again the largest population is STEMI that they are looking at. Well over one-third of their patients enrolled are STEMI patients for hospital number three. Slide number 14 shows hospital number four enrollment. You can see the numbers are less for all of these categories. The biggest population is NSTEMI for hospital number four in this situation at 94. Slide number 15 shows hospital number five with the largest group again is STEMI. But, again acute coronary syndrome being STEMI, NSTEMI and unstable angina constitute the three largest groups for this hospital as they do for our entire pilot population. Hospital number six clearly has STEMI representing over half of the cases that they have, 266 STEMI at that time followed by NSTEMI, and then lastly by unstable angina with a much lower number for stable angina. Each pilot hospital has a couple of cases of no symptoms, no angina or symptoms unlikely to be ischemic. Those are small numbers for the entire population. If we look at the projections for each of the six hospitals that we have, our volume is somewhat lower for this third year than it was for the first and the second year. We have noted a reduction in volume for the first five months of this year. Slide 17 talks about our website. As everyone realizes, at the pilot hospitals every patient who receives a PCI within 72 hours the coders go on the website where they enter the patient's registry information of over 240 fields of data. For the coders who are here I just want to remind them the only complaints we have had is when you want to log off of a case or log out of the program you have to hit the log out button which is specific, not the X. For some reason the little X in the upper corner does not work so hit the log out button. That is the only complaint we have had for the last four months for the system. We repeated this at the last meeting but it is time to repeat it again. The data that we have, after it is audited and goes through queries, is eventually deemed to be complete data, not to be changed again. It is locked down when everyone agrees to it. We have locked down the first two years of the data after intensive audits of each of the auditing cases. We are happy to say that the server that provides this website has had no down time since the last meeting. It has been up 100% so hopefully there will be no complaints received for that. Slide number 18 shows the process which I show each time so that you know. After a PCI, the data is entered into the website within 72 hours. From this it tracks two different programs. One hundred percent of cases are audited at the central office at the coordinating center. They go through a process of initial audits, queries about questions that will sometimes generate second queries with responses, and then a final data audit and final query going to lock down. Twenty percent of all cases or more receive a second audit. That second audit is a pilot site audit where one of our investigators goes to the actual hospital, pulls out the records, looks at cath logs, data, etc. and comes back from that audit with actual angiograms. The angiograms are then entered into our Xcelera Server where we then do angiographic review of those before getting back to the query program. After the pilot site audit we have additional information that is reported as we go through the charts, generate queries that then goes into the final data audit process. Information on the PCI data set is kept on our Velo Servers. Information on the statistical analysis is processed through our SAS computer system and the angiograms are stored on our Xcelera Server system for processing and review. Slide number 19 shows the audit process. The initial central audit has now been performed on over 3,000 cases. We audit a variety of things by the physician who sits down and reviews that, or by the individuals working in our central office. We look at NCDR compliance for a variety of things and make sure that there is no missing data or inaccurate or incomplete data through the central audit. Slide number 20 now outlines the pilot site audit. Remember, a little bit more than 20% of all cases get audited with an onsite pilot site audit. You can see for each of the hospitals listed here we have now performed a total of 683 pilot audits up until December 31, 2012. That represents over 20% of all cases that we have audited. The audits represent both in-hospital reviews of the charts as well as the angiograms

from the PCIs in those cases. As you know, the angiographic audit looks at diagnostic information. We have discussed this before so I won't go through it. We clearly look at the diagnostic case before the PCI to make sure that the data set in the NCDR version correlates with what we see on the angiograms for that patient. Slide number 22 looks at individual features of the PCI that we come up with including a segment of culprit lesions, whether the stenosis was confirmed, the pre-procedure TIMI Flow, lesions in the graft previously treated, lesion length and complexity. We will talk about complexity in a minute because that is certainly a focus of some of the reviews that we found. Lesion complexity is defined in the NCDR data set as the following: You can have an A or a B lesion. Those are usually short lesions that do not have a severe tortuosity or a severe angulation associated with them. A type C lesion has to meet one of the following criteria: It has to be either greater than 2 cm in length, have excessive tortuosity, excessive angulation, total occlusion greater than three months, inability to protect major side branches or degenerated vein grafts. Major side branches are defined as greater than 1.5 mm in diameter. A 1 mm side branch is not a major side branch. If it does not meet one of those six criteria then it cannot be classified as a high C lesion risk in the NCDR data set. The angiographic audit continues on slide number 24 where we look at additional things including bifurcation, and the guide-wire has to be across the lesion to count as a PCI with the intent to do an intervention. The stenosis pre-procedure and post-procedure, was a device deployed, the devices that were used, any complications, and ejection fraction if it is there. We have added quantitative coronary analysis using the QCA-Xcelera R3 Program to analyze that, we have not discussed this before but the quantitative angiographic audit is illustrated in slide number 25. Here is a circumflex coronary artery seen and what you can see is we can calculate automatically the percent of stenosis and the length of the lesion using the quantitative angiography. Now, we quantitate it by using the #6 French catheter that was noted at this time so we are calibrating it from there. The slide on the upper right shows the diameter for this lesion which is shown in the white track marks. You can see the vessel starts out well over 2 mm in size, then comes down to roughly about 1 mm diameter and then pops up again after the lesion. You will note that the diameters are measured here and 1/100 mm so we have relative good quantitation. You can see the lesion is the dip at that point in time. We have also defined not only the percent stenosis diameter which is listed down here as a 52% lesion diameter measured by the quantitative angiography, but we have also quantitated the length of the lesion. You can look here and see from these lines there is a little bit of reduced diameter as you come down the vessel. The program automatically determines the length of the lesion that we should count. The length of the lesion here is between 5 and 10 mm in the vessel. It literally is about a 5 mm lesion. You can see the quantitative obstructive length is 4.96 mm. Therefore, this circumflex lesion does not qualify as a high C lesion because it is less than 5 mm in length; that is not over 20 mm. Now you might look at this vessel and say, as an angiographer "I think there is some irregularity down here. We can call this a 20 mm lesion, or 21 mm lesion." But, we do not allow that because the quantitative program does not do that. You can see the quantitative program fills in where the lesion is here in white. You can see that most people when they look at this would say it is not a complex lesion, it is not a long lesion, there is no excessive tortuosity or angulation, and it is not a CTO at this point in time so it does not qualify as a lesion. We are following up with questions when we differ in our interpretation of type C lesion. We are sending you those pictures so that you have the quantitative angiograms to look at. We hope that this will settle some of the questions. Otherwise, it's just a guess of two angiographers thinking it is, or it isn't, etc. We do not have anything to argue. I think the quantitative coronary angiography gives us a step in the right direction at answering those questions. Slide number 26 shows an angiographic audit on a second issue.

Dr. French – Can I ask why you went to the qualitative, was that a big issue among hospitals?

Dr. Bommer – Well there was disagreement. In other words, our interventionalists who are reviewing said we believe this is not a type C lesion, but the individual dictated chart and the angiographer who performed the study at the pilot hospital says "well I think it is."

Dr. French – What percentage would that be of the cases that had strong disagreement?

Dr. Bommer – I am going to show you that in about five slides down the line if I could. I am going to show you the mis-risks and that were associated with that precise question of a type C lesion. It is about 15% but I will show you that.

Dr. French – Okay.

Dr. Bommer – Slide number 26 shows you that we quantitate this based on the fact that we check what size catheter was used and use that to calibrate the entire field. Now, when we calibrate that – this is for a #6 French catheter that we can see here – the diameter of this side branch that is shown. On slide number 26, I show an LAD lesion but there is a side branch just before it. This was claimed as a bifurcation, inability to protect the major side branch, and we measured the side branch. You can see the diameter shown on the upper right column and it varies anywhere from 0.97 to 1.36 – the diameter of that vessel in quantitative analysis. We deemed that this was not a greater than 1.5 mm vessel and therefore this was not a type C lesion. In fact the lesion was just after the bifurcation at that point. We in fact use this quantitative number to measure it and we eliminate some of those cases where it is a type C lesion because of the inability to protect the major side branch. A 1.36 mm vessel is not, by definition, a major side branch. George, you have a question?

Dr. Fehrenbacher – I would make the comment that I applaud your qualitative approach to this to try and produce some clarity in an otherwise subjective area. This has been subjective for 20 years. I have been doing this for 20 years and it has been subjective for a long time. However, the difficulty I have is the control group. Our control group is the NCDR patients who are not in the pilot study. Do you have any insight whether they are using qualitative coronary analysis to determine whether they have type C lesions or not?

Dr. Bommer – I have insight to it, I do not have data into it. I am going to discuss at a later slide a particular point related to type C that may have an effect if you can hold off until that slide. We are now using the quantitative coronary angiography to end the conversations. We had queries for them to look at again then would have to show it to another angiographer. We cannot keep showing it to another one who agrees with the file in the hospital. We are just doing this and trying to end the argument up front. I think it has been very useful. Slide number 27 now looks at the audit monitoring, which was Dr. French's question. We now look at a group of individuals – just 500 in the group – and we will expand on this. Looking at central audit, this is an audit just by looking at the data set that comes in vs. a pilot site audit where we have somebody on site looking at the angiograms, looking at the data in the patient's chart, and in log books as well. The objective for us was to look at central vs. pilot site monitoring or auditing of our PCI CAMPOS registry data. We in fact audited 500 and pulled this out of the audit group for the central audit vs. pilot site audits. Of the 240 fields that we have in the NCDR cath PCI registry version 4.3 we looked at the ones where we made changes in the data set that stayed after the lock down. That is, after all the queries everyone agreed that there was a mis-coding in that situation. If the mis-code leads to a change in the risk prognostication or prediction for the case – that is it altered the risk that affected the mortality and the outcome study – then we labeled it as a mis-risk. Now let's look at our data on slide number 28. What you see from the total number of audits, which was 500 shown here, you can see that in about 40% of the cases we detected a mis-coding when we audited that case. The mis-risks were somewhat lower at about 15%. So of the total number of audits about 15% had a change that actually affected the risk adjustment of that particular case. Slide number 29 looks at the pilot site audits. Remember, these are just audits where we are on site. We had a little under 118 at that time. Almost every time we do a pilot site audit we come up with a mis-coding. You can see that the mis-codes are relatively frequent. The mis-risks are shown in red in this column. You can see about one-third of the cases where we do a pilot audit that will come up with a mis-risk, meaning we make a change that actually alters the risk prediction or the expected risk of that particular patient that could potentially change the expected risk projection for that patient. You can see that it is usually one, two or three in that case that we are changing so you see these are small numbers. You can also see that if we sent someone out

to the pilot hospital and examined the angiograms, on as many as one-third of those cases we will make a change that affects the risk of that patient. Slide number 30 looks at the total audits. Again, it identifies the type of mis-risk. If we look at overall audits that are seen in green you will see the up-coding and down-coding shown in red against orange (or gold). What you see is after the total number of audits shown in green the next item shown is the up and down-codes. It turns out roughly the same number of up-codes and down-codes of risk are picked up on the audit. We find situations where risk is increased and we find cases where risk is mistakenly down-coded, or a lower risk is missed. Of interest, the most common up-codes that we found were in lesion complexity which is the type C lesion complexity at that point in time. Down-codes that were missed were typically something like they forgot to put in CAD presentations; they forgot to put in cardiogenic shock or heart failure or something like that. Primarily that is because when the coders go through the chart they do not see that information and they miss it. When we review the case we pick it up. So, up-codes and down-codes roughly equal the same in the total audits. Slide number 31 shows pilot audits. Again, in the pilot audits about 35% of these are in fact mis-risks identified. Again, red represents up-coding. That means we found that the original data entered predicted a higher risk for other patients. When we change that the risk actually went down for that particular patient or the adjusted risk. That is a red, or an up-coding. Gold is the down-coding and you can see again the up-code and down-code numbers numerically are roughly similar in that we found as many up-codes as down-codes when we did our audit. Of course, for the individual up-codes the number one in red is in lesion complexity. The most common up-code mistake that we found was that the angiographic person said this is a C lesion, high complexity. In review, we decided it was not. There was no support for that and we down-coded it to a B lesion or an A lesion at that time. Mistaken down-codes are scattered across a number of categories shown here including things like cardiogenic shock. It just did not get put in the coding. When we reviewed the case we said this meets the criteria for cardiogenic shock. Slide number 32 shows a summary of the mis-codes and mis-risks. If we look at the mis-codes, which are shown on the first line, you can see the central audit picked up about 0.7 cases. The pilot site rate was six times higher at 4.5. That is mis-codes per patient. If we look at mis-risk, which is the one that changes the risk assessment, it is pretty low in the central group at 0.5 mis-risk for patients evaluated and the pilot site rate came up higher at 0.7 mis-risk identified per patient in that population. We see in slide number 33 our conclusions from that. Pilot site monitoring where we are actually out at the remote site and including reviewing the angiograms detects more PCI mis-codes with an odds ratio of 6.4 times more. Mis-risk had an odds ratio of 14 times more compared to central monitoring of registry data. It is interesting that this is probably one of the first studies for PCI that actually looks at auditing and puts quantitation of what that auditing adds in the program. There are other PCI programs around the country but very few, and very few of the other states have this intensive level of auditing. Number two is the up vs. down-coding rates for PCI mis-codes and mis-risks which is similar meaning we detect as many up-code risks as down-code risks for that. Number three, the pilot site auditing of data entry, medical records and imaging improves the coding and the accuracy of our risk adjusted outcomes for these cardiac interventions.

Dr. Karmarkar – You have been looking at the mis-coding for some time now, have you given feedback to the pilot hospitals and has coding improved since we started looking at it?

Dr. Bommer – The question was where are we going with our audit in mis-code and mis-risk. We are in the process of putting all of our cases through this analysis. Right now it is a huge number because realize that we now have to track not only the original 240 fields that are in the data set but now we have to know when each of those was changed and what the final outcome was. It doubles, triples or quadruples our data set at this time. We are working with our E-Velos programmers right now to get that data. The number of data sets or data points in this is in excess of 25 million that we are looking at. Currently our reports are so large that no person on our staff can sit and look at 3,000 reports and put them into one. We are trying to process that through E-Velos and we have been working with E-Velos support programmers to do this. That is our intent but it turns out to be an enormous data set right now.

<p>Dr. Fehrenbacher – I think I made this comment before but the Massachusetts data essentially showed the same thing. People code up and code down as readily and in the end it averages out.</p> <p>Dr. Bommer – To answer Dr. Karmarkar's question, we are just saying they aim up-code or down-code because we detected something where risk was lower or higher. We are going to actually process this so we find out the final expected data result for this and can give you a number on that. We will say if we look at the original data set it was the expected adjusted risk mortality for that entire population and if we now look at the corrected data set what did that do? To answer your question, quantitatively we will have to have that individual analysis.</p> <p>Dr. Fehrenbacher – The question of if you don't think you will ever be audited, if no one will ever look at your charts, do you up-code or down-code, that has never been answered. In the Massachusetts data they all knew whether they were going to be audited or not. We know that we are going to be audited. There has never been a study in which if you know you will never be audited what do you do? That is the control group that we are comparing all these patients to. The sites that know they will never be audited.</p> <p>Dr. Karmarkar – What sites are those?</p> <p>Dr. Fehrenbacher – the sites in the NCDR.</p> <p>Dr. Brindis – That is not true. The NCDR has an auditing program that's just not as robust as the auditing program that we have in the State of California so your comment is inaccurate.</p> <p>Dr. Fehrenbacher – So tell me about the auditing program?</p> <p>Dr. Brindis – Well it has been published. We have a couple abstracts. Interestingly, similar to the comments that Bill made, and actually in the comments that you made, the accuracy of the data entered is pretty darn good other than some elements that are more fuzzy, heart failure, whatever. Our auditing strategy is not as robust at 20% as all cases get centrally looked at in terms of data quality format. That is, looked at within your hospital for example. Then there is on-site auditing using a random strategy and outlier strategy that is markedly less than 20%. Every hospital in the NCDR has the threat of audit.</p> <p>Dr. Fehrenbacher – And the angiograms are looked at and measured?</p> <p>Dr. Brindis – No. So that is an interesting question, one we could ask Dr. Bommer. Since most of the coding changes seem to be related to angiographic review . . . Although, again the fact that cardiogenic shock was missed is amazing to me because that is probably the biggest predictor related to risk adjusted mortality as opposed to a C and B lesion, for example. But one could be more cost effective in just doing quantitative angiographic review centrally without doing onsite pilot. Onsite pilot studies I am sure Bill has thought about that type of a strategy. We'll find out if it really mattered much but that could be a way of doing this.</p> <p>Dr. Forman – On a separate topic, I had one of the invasive cardiologists at our hospital who had concerns about going back and changing his original reports. If he said a lesion was 30% and then audited it and you said no its 40%, then he would get a form that says can you change your original report to now indicate that you believe it is a 40%. Then he had some concerns, probably medico legally, about going back and altering a report that is six months old that has already been in the medical record. Then, just says no it's really not 30% it is 40%. Has that come up before, has anyone mentioned it?</p> <p>Dr. Bommer – The question is changing the records. All we do is we require that we change the NCDR cath PCI data set. We are not requiring you to go back and change dictations, to change medical charts or anything else. For this registry we are trying to get the most accurate data set</p>	
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<p>that we can. When we look at that we make a change. We are not asking hospitals to go back and change their charting or their dictated notes.</p> <p>Katherine Roubidoux – Are the coders aware of this because they are sending out an extensive amount of addendums based on the requests.</p> <p>Dr. Forman – Right, because like in our hospital what happens is if that there is a question, maybe we get a progress note sheet that would go into the standard chart. We are not on electronic medical records. It says “can you sign this that now says the lesion involved was this percentage.” My assumption is that this is going back into the medical records. Is what we are doing wrong?</p> <p>Dr. Bommer – It is up to each hospital to decide what they want to do with this. All we are asking for from the central coordinating center is that when we change the calibration or the type C lesion or something like that we agree that we are changing it on the registry data set that we have. What you do back at the hospital is entirely up to the hospital staff and the physicians and your hospital however you want to handle it. We are not requiring to see documentation that you went back and changed it and noted it in the record. I honestly don’t care whether you change it in your documentation or not. Our interest is that we have the most accurate registry data set.</p> <p>Katherine Roubidoux – I believe that if they think it is not in the medical record that they are in error if they change it in NCDR.</p> <p>Dr. Bommer – No, we are not requiring that. All we are requiring is that our registry data be the most accurate it can be for this trial. You have to realize then as George eluded, lesion severity is an eyeball estimate that can vary all over the place. That’s why for 40 to 70% stenosis lesions we often require or ask for a stress test or an FFR or something like that because the severity . . . I can show all of the angiography people here a lesion and I bet I would get six different answers based on our quorum. It is a guess. You are looking at it you are saying I think it is this or that. Sometimes that guess can be changed by the emotion of the time.</p> <p>Dr. French – It shows that two readers read and you come to a consensus that is actually a fair amount of accuracy there.</p> <p>Dr. Bommer – I concur Bill, but the fact is that we go on angiographic eyeball estimates and all of that unless we look at it and say hey this number looks to be way off. Then we’re going to use the quantitative angiography to back up our call on that then we will send that back to the pilot hospital to see if they agree. Typically, when we send back the quantitative angiography they agree right away.</p> <p>Dr. French – Yes but quantitative has been shown that it is not a perfect tool either.</p> <p>Dr. Bommer – I did not say it was perfect.</p> <p>Dr. French – We just have to live with the results. I think it gives a sense of how much variation. We will not totally resolve this issue.</p> <p>Dr. Bommer – The only other option that we thought of before was bringing every one of our angio cases to the AOC to take a vote. We did bring some earlier and got concurrence at that point in time. We have thousands of these angios to review and I am not sure that time is available for you to do that. If we can move on to slide number 34. As you know, we have spent a lot of time early on regarding the criteria for selection of these patients, who qualifies, etc. In general, the pilot hospitals do a very good job at following the initial selection criteria. We did note that there were three cases in which IRB vulnerable population patients were enrolled in the study. We did notify that PI and the hospital to check to see if their IRB allows those vulnerable patients to be entered into the trial. So they needed to check with their local IRB to confirm that.</p>	
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These vulnerable patients in most IRBs are not included in IRB trials. Slide number 35 is compassionate use. We have an interest in looking at compassionate use. Anyone who is an angiographer here would realize there are patients who come in who are very high risk. Does the NCDR protocol that we have identify those high risk individuals? In the state of Massachusetts it has been shown that individuals who come in with coma on presentation, who have a ventricular assist device, who are undergoing CPR at the state of the procedure have a high risk. In that state they actually initiated a compassionate use criteria. We began using compassionate use here in California for PCI-CAMPOS beginning in 07/01/11 so each case that was done since then has had compassionate use information accumulated. On our website there are separate questions for compassionate use shown here on slide number 36. Did the patient meet the criteria and what were their criteria? So coma has to be Glasgow class less than 7 to qualify for coma. We have discussed the compassionate use somewhat previously and it is on the slides. Slide number 37 shows the results of our data entry since July 1, 2011 of matching the compassionate use criteria. A total of 1907 patients were entered and in almost all of those, but six the compassionate use questions were answered, 1901. In our pilot program you can see that 21 cases of the 1900 qualified for compassionate criteria. So, roughly a little over 1% of our patient population qualifies as compassionate use criteria in our pilot program. The most common inclusion criteria is coma. That is a Glasgow less than 7 coma class with very few numbers under LV assist devices and a few that were undergoing CPR at the time of their study. You can see that the numbers are a little higher because some were undergoing CPR and in coma at the same time. That is why the numbers don't quite add up there. A little over 1% of our patients qualify as compassionate use criteria or meet those criteria. If we look at slide number 38 you can see that compassionate use does have an effect on the population risk. You can see that if we look at the bottom line for mortality and over to the right under PCI-CAMPOS you can see that our total mortality for STEMI patients was 4.8%, typical of this STEMI population. If they came in with compassionate use under CU you can see their risk went from 4.8% up to 61.9%. It raises by over a factor of 10 the risk of having a composite event. The composite event is going to be death or, in this case, it is mortality. It really significantly jacks that up to 61.9%, that is a high risk. It is hard to get that if we look at things like intraaortic balloon pump or cardiogenic shock, you have a risk of 20 or 30% but only compassionate use has a risk of mortality as high as 60% in this population. That is the reason we included it beginning in 2011 because we thought that was going to be useful. It certainly is important when a physician is taking a patient like that to the cath lab to know that they are very high risk and certainly for the family as well. If they meet those criteria literally almost two-thirds of those patients will not leave the hospital.

Dr. Brindis – In Mass-DAC they, by definition, audit all CU cases. Do we have a similar strategy?

Dr. Bommer – We do in our population. As Ralph mentioned, for Massachusetts the numbers are comparable for mortality. In Massachusetts the STEMI mortality, which is shown here, is 4.5%, similar to ours. Mortality for compassionate use goes up to 69.8%. Very similar in numbers here in California and also in Massachusetts for these high risk compassionate use patients. We look at procedure success in Massachusetts. It went down for compassionate use from 94.2 down to 79.2%. Similarly, it went down in our PCI-CAMPOS group from 86.7% down to 47.6%. The chance of success is less with compassionate use and chance of mortality is very high in that population base. We have had discussions before about should we do compassionate use and certainly this is a high risk group, but the corollary of that is in those individuals who come with compassionate use criteria their mortality is as high as 100% if they do not receive PCI or go to the cath lab at that time. Literally, we could potentially save as many as 30 or 40% of those patients by doing that high risk procedure. We just didn't want to penalize the angiographer individual for taking on those high risk cases. Moving on to slide number 39, on your list which is shown there, this marks bifurcation in the PCI-CAMPOS program and accountability that we have done so far. I wanted to show it on this slide. "What is the Purpose of Our Quality Measurement" is the title on that. Now what you see is that there are different data sets that we have used. We started out in the first two years of this trial looking at the PCI-CAMPOS data set which is shown on the right as clinical data meaning 240+ fields of clinical information. This includes angiographic criteria and descriptions, etc. for PCI-CAMPOS. In the first two years we compared

our PCI-CAMPOS data with administrative data shown on the far left that was accumulated by the Office of State Healthcare Planning and Development (OSHPD) which is known as the patient discharge data. That data is usually generated for coding for payment reasons or quality improvement. We have now switched from our comparison in the first two years of PCI-CAMPOS to PDD data which we presented at every prior meeting. Since we have acquired the NCDR California data set we have stopped using the OSHPD-PDD data and we are now using our comparison on the right for PCI-CAMPOS with the NCDR registry data for California and the NCDR-US data at that point in time. Now, that means we are using what we hopefully call apples to apples. We are using our rich clinical data set with the rich clinical data set of California NCDR data set which we will go over. We believe that this gives us better data quality. We believe that it gives us better risk adjustment and, as you can see, it also costs us more money. We appreciate the AOC in making the recommendation and approving the process of allowing us to generate and get that NCDR California data for that. We believe it proves our overall accountability analysis and potentially moves us to the point where our data is accurate enough that we could consider public reporting. Next slide will detail what we are doing in our new analysis which is now “apples to apples” – NCDR California vs. NCDR PCI CAMPOS data sets. We now have in our study 122 California hospitals that we have analyzed. We have analyzed the NCDR California data which represents that we have separated it out. These are the hospitals that are not in the PCI-CAMPOS program. There are 116 hospitals that we have the data for all PCIs in California that are not our PCI-CAMPOS hospitals. We followed those or looked at that data for 24 months so we have two years of data here. We enrolled in the NCDR data registry for that period of time. There were almost 100,000 cases – 99,300. Of interest, we looked at how many of these were STEMI. You can see in California in general 17.7% of all PCIs in the large registry of 116 hospitals are STEMI patients. That compares with the PCI-CAMPOS program which is shown down here in blue and the PCI-CAMPOS program again we followed for 24 months. We were slightly off by one month on this but we wanted to have 24 months, two years to two years comparison for that. We have six hospitals in PCI-CAMPOS with 47 operators. In that two-year period we completed 2,601 PCIs. Of interest, whereas NCDR was about 17% STEMI we have almost doubled that population of STEMI at 32% in our PCI-CAMPOS program. You can see that the difference here is in PCI-CAMPOS we treat more STEMI, roughly twice the number of STEMI population compared to the rest of California at that time.

Dr. Brindis – This is just a head check for me, my understanding so you can correct me – So on the last slide number 40 there are about 151 hospitals in the State of California that do PCI, is that pretty accurate?

Dr. Bommer – That does any PCI, that is correct.

Dr. Brindis – So 122 therefore are in the NCDR of that 151, is that the assumption then?

Dr. Bommer – There are 122 hospitals in NCDR.

Dr. Brindis – And 29 are not?

Dr. Bommer – Correct. If you look at the numbers here we have picked up 99,000 cases at that point in time. Almost 50,000 a year. If you look at the PDD data which picks up those other hospitals we missed and look at their total numbers, it's about 50,000 per year. In those 29 hospitals we are missing it's a very small number of PCIs that we're missing. I believe those 29 hospitals are pretty much doing a small number of PCIs. I believe that most of the high volume PCI programs in California are in our data set and are in the NCDR data set. We plan on getting you those exact numbers from those hospitals that are not doing it as well.

Dr. Fehrenbacher – Has everyone looked at NCDR vs. non-NCDR participating hospitals in what the outcome data, etc. is?

Dr. Brindis – Our experience is we have about 85% of the national PCIs performed in the NCDR

<p>but the general experience is its low volume centers overpopulate the ones that do not participate.</p> <p>Dr. Fehrenbacher – But there has never been a quality look at this?</p> <p>Dr. Bommer – I am not aware of any publications on that. I can tell you that we have plans to look at that information in the State of California. Slide number 41, as I said we are richer in STEMI than the rest the other California hospitals. Obviously, STEMI comes out as a significant difference with CAMPOS having significantly more STEMI. We also have more emergent PCIs, more smokers, more dyslipidemia, more CAD history, more class 4 heart failure, more heart failure, more chronic lung disease, more cardiogenic shock, more thrombosis and more TIMI-0 Flow at initiation of the study as would be seen with more STEMI population at that time. All of these are significant differences in the case mix between California and PCI-CAMPOS. They are statistically different. I have to say, we do not have exactly the same case mix as the rest of California when we go through our next slides.</p> <p>Dr. Karmarkar – Could that just be because of the audit process? Do these other hospitals not go under such a rigorous process that we go under?</p> <p>Dr. Bommer – For STEMI, no, I would guess that STEMI are accurately reported.</p> <p>Dr. Karmarkar – What about the other categories such as family history, etc.?</p> <p>Dr. Bommer – It is entirely possible that our intense audit system may differ from the less intense audit system of the NCDR for regular acute hospitals.</p> <p>Dr. Brindis – By the way, there is a manuscript looking at that equality NCDR registry in JACC in the last six months and I would be happy to send on that article if people are not familiar with it.</p> <p>Dr. French – Statistical significance against clinical significance. Some of these are not really clinically significant. Clearly the thrombosis and TIMI Flow may request a STEMI but some of the other data is only 2% difference and really clinically is not significant. You need to keep that in mind as well.</p> <p>Dr. Bommer – Absolutely correct and we are going to try to correct that when we look at our Observe and Expected rates and then we do risk adjustment because the risk adjustment will go through these numbers here. It is our best attempt to level the playing field for it. I just want to make a point that our populations are a little bit different for PCI-CAMPOS where we tend to treat more STEMI and some of those patients are higher risk. Now the next slide number 42 shows you the situation for risk factors where CAMPOS actually had lower risk factors associated with it. In order words, we had a little bit less hypertension, diabetes, prior MI, prior valve surgery, prior PCI, prior CABG, diagnosis, renal disease, left main disease, ejection fraction and high C lesion than the rest of California. Now, I show this because I know there will be questions. If we look at our data set for PCI-CAMPOS with these parameters we have a little bit lower risks. One of those is high class C. Notice that in CAMPOS we have 34% patients qualify – a little over one-third as high – C lesion. The rest of California is 55.9%. The question remains: Is the rest of California seeing a much more complex lesion or is this because of coding at that point in time? Is it because we have been rigorous and our coders know they have to show us information that it is high C that we have chiseled this down from a higher number to 34.1%? I think that's a question that will be asked when we look at this data.</p> <p>Dr. Karmarkar – I also think the ejection fraction issue, you self-selecting patients out of CAMPOS. If noninvasive studies show by echo or nuclear EF is less than 25 or 30% we do not do the procedure at our hospital, we just send them to a different hospital.</p> <p>Dr. Bommer – Correct.</p>	
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Question – Where do all the STEMI fall in? Aren't they high C?

Dr. Bommer – No.

Dr. Brindis – That is a great question, I was going there myself.

Dr. Bommer – No, a STEMI would not be a high C. It's not a chronic total occlusion, it's not excessive angulation, it's not excessive tortuosity, and it's not necessarily a degenerative vein graft at that point. Once you open the vessels, you put the wire through and you do the balloon dilation, if the lesion is less than 20 mm in length then it is not going to qualify as a high C.

Dr. French – Right and that's why none of us use A, B or C anymore. It's not a viable classification system. It has been disproven. I realize it was part of this study but in reality . . . The STEMI lesion is . . .

Dr. Brindis – Maybe when we look at the data separated vs. Non-STEMI we can get a better handle on this.

Dr. French – Why describe it showing as some lower risk because when you put more STEMI there they tend to be lower risk, they tend to be younger. There are a lot of issues like that. These are not perfect populations as you are pointing out and I think we have to live with that.

Dr. Bommer – The point of this slide is just to acknowledge up front before we do our risk adjustment. These are somewhat different populations. I just wanted to document it. As you said Bill earlier is that these are statistically significant because we have 100,000 patients in the study. Some of these are relatively small clinical differences that we would have here. High C is an important issue because it can increase the risk adjustment by a significant factor of 1-1/2 to 2 so it will play out as a risk factor in our analysis. Slide number 43 shows in these variables age, gender, BMI, cardiovascular disease, peripheral disease, proximal LAD and balloon pump there was no difference in the population. For these parameters or variables we are actually no different than the rest of California. That is, PCI-CAMPOS and California are the same for those. Hopefully there is no controversy on those items. The last thing is we will now talk about observed outcome statistics. Remember, these are observations before we get to the correction process. Our composite outcome, if you remember two meetings ago, we decided to make our primary outcome in-hospital death and emergent CABG. It is the combination of those two as our composite. If we look at the State of California in the NCDR data set that event rate occurred in 2% of the population. For PCI-CAMPOS it occurred in 2.5% of our enrolled patients. The statistical difference in the observed composite outcome was not significant at 0.07 at that time. So no difference in composite outcome of California vs. PCI-CAMPOS for observed composite outcome. For in-hospital mortality remember that's one of the components of the composite. NCDR California total mortality 1.75% and for PCI-CAMPOS 2.15%. The p-value was not significant for that as well, meaning no difference between these two populations for mortality and composite outcome. The last thing is emergent CABG. There was 0.29%, a very low rate of emergent CABG in California, and for PCI-CAMPOS it was also low at 0.35%. But, that was statistically significant with a p-value shown at 0.0001.

Dr. Brindis – I have trouble understanding how a difference of 0.4% mortality would not be significant yet a difference of 0.06% in terms of emergency CABG would be. That could not be clinically relevant. Can you comment on that?

Dr. Bommer – We are looking at the variability here. In other words, NCDR is not all at 2% +/- a little bit but it's a wide spread. Because it's a wide spread the spread of our PCI-CAMPOS fits within the two standard deviations. Or it fits within the population so that you can say the populations are not significantly different. I will provide you even better data as we go along here. If you can hold off for just a little bit I think it will be intriguing. What we can say is statistically the

<p>populations of NCDR California and PCI-CAMPOS are not different in composite or mortality events. The number that we see here, 0.3%, for those going to surgery is typically what we have seen in other big trials. It is a very small number and that was one of the concerns of off-site hospitals. How many have to go to emergent surgery? It's a fairly small number for both California as well as the off-site hospitals and PCI-CAMPOS. To answer your more statistical question I am going to ask Dr. Li to come up to answer your questions and to proceed with the rest of this. He is now going to talk about basically the risk adjustment process that was made in the study. I believe that the risk assessment, or the risk adjustment, based on this will provide even more complete or accurate data.</p> <p>Dr. Li – With respect to your question Dr. Brindis, why is the difference 0.04 but the P test is significant? The test here is a Chi-Square Test. A Chi-Square Test is comparing the difference in the mean relative to the variation within each group. If this difference between the mean is significantly larger than within groups, then the p-value will be significant. Here is the case. Even though the difference in the mean is so small but relatively to the within group variations is still a lot higher. Let's go to the next slide which is slide number 45. In addition to composite event, we are now also able to check for other outcome measures. This though we have never done with PDD data. Here we list 18 other outcomes like MI biomarkers.</p> <p>Dr. Bommer – If we could just announce for the remote sites, we are on slide number 45.</p> <p>Dr. Li – Everything I marked as red shows that PCI-CAMPOS has a significantly higher outcome rate compared to PCI NCDR. About 50% of those 18 measures. So in nine measures we show significantly higher. Of course this is the observed outcome. As we see our cases profile in the CAMPOS is significantly different from the NCDR California. We have more STEMIs. I am not surprised we have significantly higher other observed outcome compared to their situation. That is why we have to do risk adjustment, otherwise there is no fair comparison. Let's go to the next slide which is slide number 46. We are doing the risk adjustment now. We have two years' worth of data even though our CAMPOS is one month later compared to the NCDR California. In total we have even more than 100,000 cases. Our observed composite event is 2.02%. The risk factors will cover demographics, prior PCI clinical conditions as well as the lesion risk. As we develop the risk model we will look by varied analysis to examine one by one relationship. One will be a risk factor and another one will be composite outcome. Based on that, we developed parsimonious model which only contains the risk factors that are statistically significant risk factors. Based on bivariate analysis as well as a parsimonious model we developed the refined model. This is the model we are going to use for risk adjustment. On slide number 47 we are showing the results of bivariate analysis results. Here there are 22 variables we found that were significantly related with the composite events regardless of other factors. That is one by one: Age, gender, BMI, PCI status, CAD, insulin diabetes, NYHA IV classification, prior heart failure, dialysis, CVD, PAD, lung disease, etc. These are the individual risk factors we found by the bi-variate analysis.</p> <p>Dr. Karmarkar – Specifics of the coronaries RCA/RPDA/RPL, do you mean obtuse marginal rather than acute marginal stenosis? Circumflex obtuse marginal?</p> <p>Dr. Bommer – No it is right coronary artery. Obtuse would be a CIRC lesion. Interestingly, that is all the rights. There is proximal LAD in there but we left circumflex off the map. That is in the bivariate analysis.</p> <p>Dr. Karmarkar – Okay.</p> <p>Dr. Li – Next slide number 48 shows two columns. The column on the left is insignificant risk factors by varied analysis. We found four of those: race, recent smoker, prior valve surgery and pilot status, which is CAMPOS vs. NCDR. Those four variables by bi-variate analysis did not show any significant statistical effects of the composite event. On the right-hand side we have significant risk factors but protective or counterintuitive risk factors like hypertension,</p>	
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dyslipidemia, family CAD history, prior MI, prior PCI or prior CABG. Those six variables by varied analysis shows that if patients had more of those cases then they tended to have less composite events. That's why I said it is protection or a counterintuitive. We have to think about whether or not we need to include them in the risk model, whether or not those factors really reflect the patient's sickness before the PCI. Then we built the parsimonious model. As we saw by variate analysis we have a 32 variable there. All will be a candidate risk factor. We put composite events as a dependent variable. All 32 candidate variables are in the model then we through a parsimonious backward selection process. At $\alpha=0.1$, we asked the software through the backward selection among those 32 risk factors. Then we have 24 significant risk factors left in the multivariate model. Four of them we found continued to be counterintuitive which include dyslipidemia, family CAD history, prior PCI and prior CABG. As you can see, the chart on the left-hand side shows the odds ratio is less than 1. That shows after controlling for all other variables if the patient had those four, then they actually have less risk to get a CAMPOS event. As you can see in the model with 24 significant risk factors we have a C-statistic of 0.9 which is very high. This is very good. This discrimination power is ideal actually. However, the Hosmer-Lemeshow test for calibration is significant, less than 0.0001. The calibration means the predicted number of the composite measure when compared to observed composite measure they should match. But there is a significant difference. That is something we have to think about. There is another reason for the small p-value, that is because of a large sample size. The Hosmer-Lemeshow test is a Chi-Square based test. Chi-Square based test is always sensitive to number of cases. When you have a lot of cases like what we do, more than 100,000 cases, a little bit different could add it up so it makes a significant difference. That could be another reason for a significant p-value through the Hosmer-Lemeshow test.

Joseph Parker – I have a question about that significant difference. When looking at the deciles of predicted risk.

Dr. Li – I am going to present it later.

Joseph Parker – Okay.

Dr. Li – Before we move on to the refined model I also used a different data set that is NCDR California only. Those are 99,000. The calibration test is the same and even the C-statistic is the same, the risk factor of the 24. That makes sense because CAMPOS data is only 2,600 vs. 99,000 so they have more weight. The model, even though not the entire population but with only using NCDR data we have a similar model.

Dr. French – Are we on slide number 49?

Dr. Bommer – No we are on slide number 51.

Dr. Li – Now we are on slide number 51 and we are talking about the refined model. As I said before, based on the parsimonious model, based on the bivariate analysis, we can develop a refined model and see whether or not we can improve discrimination as well as calibration. The refined model I removed the four counterintuitive risk factors. If a patient has hypertension how come they have less of a composite measure? It does not make any sense. We kick out all those counterintuitive risk factors but add thrombosis as a significant risk factor because when we do a bivariate analysis we saw that this is a significantly independent variable. So, this refined model ends up with 21 risk factors. As you can see on the left-hand side of the chart there is no longer a counterintuitive risk factor. Most significant predictors from this refined model are PCI status, IABP, cardiogenic shock as well as renal failure. These are the most significant risk factors with an adjusted odds ratio of more than 2. Now let's go to slide number 52 which has two criteria. One is very good discrimination power that is also called a predictive power as well as calibration. The C-statistic with 21 variables without a continuity of variables is 0.902, also very good. The Hosmer-Lemeshow test still shows p-value less than 0.0001. That now leads us to take a look further where this difference comes from so we need to do a calibration analysis by

<p>risk group. Let's go to slide number 53.</p> <p>Dr. Jain – If in the bivariate analysis lesion complexity ended up as a thrombosis would it make a difference?</p> <p>Dr. Li – That variable is also listed in the multivariable logistic regression model. Yes, that is a significant risk factor too. They are not excluded.</p> <p>Dr. Jain – My question is. Why would we only use thrombosis and not other?</p> <p>Dr. Li – Yes, let's go back to that slide. Go to slide number 51. You can see the high C lesion has a significant odds ratio of more than 1.</p> <p>Dr. French – Okay that is the variable.</p> <p>Dr. Li – For the thrombosis, fourth from the bottom, from bivariate analyses we saw that was significant but now when we enter that it does not hurt anyone treated for the thrombosis patient. It is not counterintuitive either. That variable would stay in the multivariate model. Does that answer your question?</p> <p>Dr. French – Yes thank you.</p> <p>Dr. Li – Now we go back to slide number 53, that is calibration. We do a further analysis by the risk group. Now as you can see, what I colored is red decile 4 and 8. We can see we have a little over predicted events compared to what we observed. For example, for decile 4 that is a risk group. We have 10,000 cases there. We observed 21 composite events, however, we predicted 34. The difference is 13 different cases. However, when we calculate the expected range you have 95% of predicted events. The event ranges between 22.7 to 45.6. Still the 21 observed events are less than the predicted event. That means for that sub-risk group we are a little over predicted composite events. Similar to number 8. We predicted 143 cases but we observed 95, an over prediction. However, on the risk group 10 we have underestimated compared to the observed almost 1,500 cases. By the decile analysis we now say there is 7 of the 10 sub-risk groups where the predicted number of events matched the observed; however, three of those are kind of off. They are either up or low. I had a note, two risk groups, 4 and 8, fall below the expected range and another one that is decile 10 falls about the expected range. But overall you can see the total, there are 101,933, observed event is 2,054, predicted 2,054 and difference is 0.</p> <p>Dr. Arnold – For those of us who are statistically challenged, is this exercise to demonstrate the validity of the method?</p> <p>Dr. Li – Yes the risk model has to be two criteria – One, it has to be very good in prediction power. That means when we pair, one had to complication and one without. How many times, the predicted rate for the patient who had a composite event, higher than the patient that was without composite event. We have 90% time, we correctly predicted those patients with composite events. Another criteria is calibration. The total predicted number has to be same as the total observed composite event. Here was say, yes, overall we did not see systematic underestimated or underestimated. Even though we found three groups but generally speaking there is no systematic over predicting or under predicting. That concluded the model that it's good. We are running over on the judgment for the risk model. We use that refined risk model and now we can rate provider performance.</p> <p>Dr. Bommer – Slide number 54.</p> <p>Dr. Li – With the refined model we can calculate each patient predicted composite event then we add it up by hospital. We get the expected for each hospital. Then we use the observed divided</p>	
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by expected and then times population rate to get a risk adjusted event rate. Using that methodology we can now see how the performance is once we adjusted the patient's risk factor. There were 102 hospitals in this study. For NCDR California we found 116 hospitals from the NCDR. We found the majority of them, 105 actually performed as expected. We do have four better hospitals with risk adjusted event rate of 1.02. We had seven worse NCDR California hospitals with average risk adjusted event rate more than 3%. Please notice; those worse hospitals are not necessarily a lower volume hospital. They range from a volume of 277 to as high as 3,000 for three years. Next slide number 55, and with the same rule you could measure CAMPOS. We found five hospitals as expected with average risk adjusted event rate 1.67. We also have one better hospital with risk adjusted event rate of 1.15. That is the reading based on all PCI cases in two years. Next slide is number 56. Now we took just two groups. One is NCDR California and the other is CAMPOS because that is the pilot purpose. We did a general comparison. In terms of volume, on the left-hand side is the chart and on the right-hand side there is the test. In terms of volume, NCDR California all 116 hospitals averaged for two years 856 cases. In the CAMPOS we had 434 cases but the p-value is larger than 0.05. That means there is no significant difference between these two groups, NCDR California and CAMPOS. You can see from this chart even though the difference in the mean is 400 you can see the variation within the group is huge. Some had very low and some very high. The mean difference compared to variation within these two groups shows no significant difference. Slide number 57 we also compared the observed event rate between NCDR California and the CAMPOS. For NCDR California we had observed composite event of 3.18% compared to CAMPOS at 2.48%. But statistic testing shows a p-value of larger than 0.05 so no significant difference to expected event rate. On slide number 58 the expected event rate for a NCDR California is 2.55 but for CAMPOS it is 3.04. Within the group there is no significance but we know why we had a higher expected composite event because we have more STEMI cases. Now looking at slide number 59 for NCDR California on an average of 116 hospitals we showed 2.11% for risk adjusted composite event vs. CAMPOS at 1.58%. But testing shows do not have a significant difference between these two groups. Going to slide number 60 is talking about STEMI excluded. If we based it on the total PCI we would have 122 hospitals in the population but when we measure the STEMI excluded we now had 121 hospitals left. For NCDR California the total is now 115. We have 106 hospitals as expected with an average risk adjusted event rate of 1.11. Four better hospitals were with an average risk adjusted event rate of 0.58. Then there were five worse hospitals with risk adjusted event rate at 2.55. Also, notice that the worse hospitals are not necessarily a lower volume hospital here. They range between 219 and as high as 522. The next slide, number 61 shows the CAMPOS. When we measured STEMI excluded PCI cases for the two years there was no one that stood out, either as worse or as better. On average we had 1.15% risk adjusted on composite event. On slide number 62 there is a similar analysis but we are restricted in our comparison rate with the STEMI excluded cases. Total volume for NCDR California is 711 average hospital volume in STEMI excluded PCI. For the CAMPOS it was less than 300 with a p-value larger than 0.05, and this is not significant between the two groups. On slide number 63 for STEMI excluded for NCDR it 2.98% and for CAMPOS it is 1.28%. The test between the two groups also were insignificant. Slide number 64 compares the expected event rate between two groups for STEMI excluded. NCDR California 1.77% and CAMPOS 1.38% which is slightly higher but p-value is not significant for this variable. Slide number 65 for the PCI risk adjusted event rate shows the NCDR California at 1.16 average risk adjusted event rate from 115 hospitals. For CAMPOS six hospitals was 1.15. The test between these two groups are not significant. On slide number 66, the physician ratings we have no information from NCDR California so this rating remains within the CAMPOS data. We have 47 operators in the CAMPOS, one stands out better with less than one risk adjusted composite event rate. We also have the rest of them, 46 of the operators on average had an adjusted risk event rate of 2.09.

Dr. Brindis – This includes STEMI?

Dr. Bommer – Yes this includes STEMI. This is all PCIs.

Dr. Brindis – And this data does only include the physician volume at a CAMPOS hospital as

opposed to their physician volume total within other hospitals?

Dr. Li – Yes, because the NCDR marked off those operator fields when we got data from ACC. The next slide is number 67. We compared the performance for CAMPOS physicians for the STEMI excluded. Of the 47 operators 41 operated on those STEMI excluded cases with average risk adjusted event rate of 0.88. There is no one that stands out, either better or worse performance. Slide number 68 shows the total volume and the composite event relationship. On the left hand side we did an analysis by hospital and the right hand side is by CAMPOS operator. For the hospital we had 122 hospitals. We did not see any p-value less than 0.05 except the expected event rate where we had a statistically significant difference which shows the higher volume which tends to have a lower composite event rate. Others like the observe event rate or the risk adjustment event rate there is no significant effect whatsoever in terms of PCI volume. On the right-hand side, among the CAMPOS operators we did not see any statistically significant relationship between total volume and the composite event. On slide number 69 when we limited our analysis to study STEMI excluded we had the same picture. By hospital, we had 121 hospitals that did STEMI excluded cases with an expected rate where we found more STEMI excluded cases performed by the hospitals that tend to run lower expected event rate but the rest of them for observed or risk adjusted there was no significant relationship. By the operator, which was limited to the PCI CAMPOS only, we did not find any significant relationship between volume and a composite event. Now going to slide number 70 the statistical analysis summary, the first thing we notice is that NCDR California and that CAMPOS had a very different case profile. One thing we noticed is that we have much more STEMI cases compared to NCDR California. However, after we do a risk adjustment based on the total PCIs overall was with a significant difference between NCDR and CAMPOS hospital. The NCDR California hospital was 116, they had 4 better and 7 worse outlier. Our CAMPOS was among 6 hospitals, had 1 better and no worse hospital. CAMPOS operators was 47 with 1 better and none worse. Slide number 71 shows risk adjusted composite rate based on STEMI excluded and overall showed no significant difference between NCDR California and the CAMPOS overall. Within the NCDR we found four better and five worse outlier hospitals and with the CAMPOS hospitals there were no outlier hospitals and no outlier operators either. Slide number 72 shows no significant relationship between the hospital or operator PCI volume and the risk adjusted composite event. This concludes my presentation on the statistical side of risk adjustment. One more thing I want to make record of, I want to congratulate the AOC who made a decision to buy NCDR data so now we really have “apples to apples” comparisons. My final words I want to say, we received this NCDR data and there is a tremendous challenge because not only the variable is different but also the format is very different. I want to congratulate Geeta Mahendra, we are happy to have her to beat that challenge. She did an excellent job to make the two data sets comparable. I appreciate it.

Dr. Bommer – Thank you very much and as Zhongmin had mentioned this comes to us in pipe delimited format so it was Geeta who was aligning those pipes for over a month to try and get them all in the right places. If you get a data set that is 20 million sets of data it is quite a task to sit down there, you get a spread of numbers and then try to get them back in line and aligned. She did it under a tight time line at that point in time. We were going to take a break for lunch but it is not here?

Dr. French – STEMI analysis patients only if you exclude them they are going to be the same?

Dr. Bommer – No, what we did in the initial presentation did not include every separate group so we did the overall group in which you saw and after risk adjustment there was no difference. We also looked at the STEMI excluded group because one-third of our patients, remember are STEMI, and in the STEMI excluded group there was no difference. We can go back and look at STEMI only or NSTEMI only, etc. and do any of those analyses, but our original premise when we were several meetings back was we wanted our primary outcome to be overall composite events in overall patients and in STEMI excluded. So, we can change that as we go along. We

<p>could obviously do an analysis for any one of the variables that we have here today if the AOC decides they want to go in that direction.</p> <p>Dr. French – I would strongly suggest that as we found most of our patients are more STEMI weighted than . . . You need to look at that . . .</p> <p>Dr. Bommer – Right but my suspicion is because the overall group is no difference and the STEMI excluded is no difference that there will probably be no difference in the STEMI alone.</p> <p>Dr. French – I understand that but I think we need to look at that better.</p> <p>Dr. Bommer – Okay. So we were going to take a break for lunch but it's not here yet. What we would like to do is continue and for those people at the remote sites if you want to eat while we talk that is perfectly fine with us, we'll accept that.</p> <p>Dr. Way – I would just like to ask that if any of the members of the PCI Committee are going to leave the meeting permanently please let us know. We wound up with people who had to leave the meeting last time and we were not aware that they were not present. It only affects us in so far as we have the ability to have a quorum which allows us to actually do business. So if anybody is going to leave please let me know, otherwise we will just continue. We are, according to the schedule, going to have a lunch break at 12:30. At which time the presentation from UC Davis would be completed or not?</p> <p>Dr. Bommer – Absolutely and we'll get right on with that. I would like to introduce Dr. Ram who has spent two years with us going over all of the data and everything and he is going to present some of the quality metrics. We've talked about "performance metrics" which is the composite outcome and mortality in the data. But now we are going to drift into what's called quality metrics and he's going to discuss additional things like stress testing and preoperative medicines or discharge medicines that were offered in these individuals, Dr. Ram.</p> <p>Dr. Ram – Thank you Dr. Bommer. We are currently on slide number 72 and we are getting to the quality metrics. This slide deals with postoperative medication use and three of those were taken into account. The first one, aspirin, prescribed at discharge. In our CAMPOS data we had 99.0% compared to the national data for NCDR. We fell within the range of their 25th–75th percentile. Thienopyridines prescribed at discharge in patients with stents. In the CAMPOS data we fell at 99.8% which was also within the 25-75th percentile. Lipid lowering agents prescribed at discharge, we had 97.1% which was actually a little bit better than the 75th percentile compared to national NCDR.</p> <p>Dr. Fehrenbacher – How are you capturing non-thienopyridines? Some of the newer oral antiplatelet agents that are not thienopyridines.</p> <p>Dr. Brindis – Or did you put them in that category but not properly label that category?</p> <p>Dr. Ram – Yes, it also includes the other P2Y12 inhibitors.</p> <p>Dr. Bommer – So it does include Ticagrelor and Prasugrel in that classification, it was just the label there was originally on the first one listed as thienopyridines. It implies that all of those patients in that had dual antiplatelet therapy after PCI or stent.</p> <p>Dr. Ram – Going on to slide 73. This slide deals with stress testing and the number of elective PCI patients was a total of 433. Elective patients who had a stress test, imaging study or FFR performed was 294 overall. Standard exercise stress test, patients who had positive results, indeterminate, and the total. We had 53 positive results, 13 were indeterminate and that was 75 total. Stress echo, we had a total of 17 and out of that 15 were positive, 2 were indeterminate. SPECT, we had a total of 194, 158 positive results, 15 indeterminate. CMR, we had one and that</p>	
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<p>was a positive result. FFR with results less than or equal to 0.75, total was 15 and we had 6 that met that criteria. The proportion of positive stress tests or imaging studies out of the number of elective PCIs was 231 out of 433 which came to 53.3% overall.</p> <p>Dr. Brindis – So does that include the six patients that also had a positive FFR, that last line?</p> <p>Dr. Ram – Yes, it does.</p> <p>Dr. Brindis – It's not written like that so I just want to make sure.</p> <p>Dr. Karmarkar – With 100 positive stress tests, does it include a positive FFR?</p> <p>Dr. Bommer – Yes, it's how to label that. It's positive stress test. If you think of FFR as sort of a limited adenosine stress then it's sort of a test.</p> <p>Dr. Karmarkar – I also don't see IVUS on here which we do from time to time, positive IVUS intravascular ultrasound.</p> <p>Dr. Bommer – So the question is whether IVUS is a positive stress test or not and we looked at that. We do know there is one center that had some IVUS'. We were sitting there and actually talking with NCDR what number on an IVUS constitutes a positive stress test was the question, and I don't have that answer.</p> <p>Dr. Karmarkar – It correlates with a positive . . . hemodynamically significant lesion.</p> <p>Dr. Forman – The elective PCI _____ was unstable angina?</p> <p>Dr. Bommer – No.</p> <p>Dr. Forman – That's considered an elective PCI?</p> <p>Dr. Bommer – No, for the stress test this has to be someone with stable angina who in fact comes in because they have been identified as an abnormal or positive stress test. That is the appropriate use criteria actually for doing the PCI in a stable angina patient, is to have a positive stress test. Now, of interest here is that the NCDR 25-75th percentile is 50-72% so we are in the range of the 25-75th percentile of the national numbers for those use criteria.</p> <p>Dr. Fehrenbacher – I have a question about FFR. I see your cutoff is 0.75 with a two trial suggesting 0.8 as a multi-vessel cutoff. Do you have any comments on that?</p> <p>Dr. Bommer – Yeah, we can look at whatever number. I think we picked the number that we had from NCDR at the time. We will get back to that. It is between 0.75 and 0.8 depending on what trial you look at but if you look at that it is not going to affect by a hill of beans because out of a total of 2600 patients we only had 15 who had FFR at all so it is a very small number.</p> <p>Dr. Fehrenbacher – The data is not accurate actually.</p> <p>Dr. Bommer – You mean you do more FFRs?</p> <p>Dr. Fehrenbacher – Yes. At my hospital, Humbolt two, it's zero. I do a lot more FFRs.</p> <p>Dr. Bommer – So somehow they are not being coded on your coding chart. There is a field in there and we should meet with your coder to make sure they are entering it into the appropriate code because they may not know where to put that coding.</p> <p>Dr. Fehrenbacher – Is that true for your Dr. Arnold?</p>	
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Dr. Arnold – Yes.

Dr. Bommer – I would suggest for the PIs who are here or available if you could go back to your coders and say remember to code for FFR because if the box is not checked we cannot identify it. Of course for FFR you may not have recorded it on angio or anything so there is no way we can pick that up.

Member of Audience – Sometimes it is difficult to find the stress test. Along with that the risk level and for determination of the risk. I know the coders look for that but sometimes it's difficult to find the actual determination of risk. If the interventionalist mentions it in their workup that will help the coders.

Dr. Ram – Okay, going onto slide 74. This is dealing with the door to balloon time in STEMI patients. Median time to immediate PCI for STEMI patients in minutes overall was 65 which fell within the 25-75th percentile range for NCDR nationally which was 55.8 to 67.0 minutes. The proportion of STEMI patients who received immediate PCI within 90 minutes was overall 92% which also fell within the 25-75th percentile nationally which was 87.0 to 96.8. The percentage of patients having emergency CABG overall was 0.3% which fell within the range of the 25-75th percentile nationally which was 0 to 0.4%. Acute kidney injury overall was 2.7% which also fell within the same 25-75th range. Going on to slide 75, post-procedure stroke overall was 0.3% which was at the 75th percentile nationally. Composite which included death, emergency CABG, and stroke, overall 2.7% which also fell within the national range 25-75th percentile of 1.7 to 3.3%. Median post- procedure length of stay for PCI with STEMI overall was 2.5 days which fell within the 25-75th percentile of 1.9 to 2.8. Median post-procedure length of stay for PCI without STEMI overall was 1.1 days and there was no comparison date available. Creatinine assessed pre and post PCI overall was 92.0% which fell within the 25-75th percentile range which was 75.9 to 93.2%. Transfusion of whole blood or RBCs overall was 3.3% which was outside of the 25-75th percentile range of 0.7 to 2.5%.

Dr. French – There are two outliers there are quite dramatic.

Dr. Brindis – They may be hospitals that have a higher STEMI percentage. Is that true?

Dr. Fehrenbacher – I'm hospital two; we had a 5% transfusion rate. We were alarmed at that and went back and looked at why these patients were being transfused. Well, the patients that were being transfused were the cardiogenic shock patients, the patients who came in with a hemoglobin of 7. We had a very low hematoma requiring transfusion rate. These were all very sick patients, often anemic to start with which is associated with having a STEMI because of poor medical care. So, I would be interested to see if you think that is an outlier you need to look at the risk adjusted transfusion rate.

Dr. French – Well, it's definitely an outlier?

Dr. Brindis – Hospital six, is that also a high STEMI hospital do you know?

Dr. Jain – Hospital six is also 50% STEMI rate so we do have very sick patients coming into the ER. We get a lot of Integrilin, Plavix and aspirin so certainly at more risk for bleeding post-procedure. We are looking at this to see what we can do to decrease the transfusion rate and bleeding rate for sure.

Dr. French – You want to stop Integrilin?

Dr. Jain – We are trying to see if the dosing of Integrilin and timing of Integrilin if we can reduce that and see what else we can do to improve this.

<p>Dr. Brindis – Do we have data on the use of transradial approaches in the six hospitals?</p> <p>Dr. Jain – That is another thing we are thinking about is transradial approach in the future, especially for high risk patients.</p> <p>Dr. Fehrenbacher – It turns out in our hospital transradial wouldn't change it at all because these were not access site-related bleeding. It was gastrointestinal bleeding and very commonly anemias to start with.</p> <p>Dr. Ram – Okay, going on to slide 76 looking at intermediate stenosis lesions which were lesions of 40-70% with IVUS performed on those patients overall was 6.6%. We had no comparison data. Intermediate stenosis lesions with FFR overall was 9.7%. Again, we had no comparison data. Biomarkers assessed post-procedure for elective in-patients overall was 70% which fell within the 25-75th percentile range of 13.3 to 77.2. Post-procedure MI overall was 6.5% which was higher than the 25-75th percentile range nationally. Going on to slide 77 this slide is dealing with the rates of PCI success. Number of patients overall was 2,601. The number of lesions treated was 3,542. The guide wire crossed the lesion in 3,469. Post-procedure stenosis of less than 20% was found in 89.7% of those cases. Post-procedure stenosis of greater than or equal to 20% was found in 8.2%. Post-procedure TIMI-3 Flow was 93% and the amount of lesions which had less than 20% stenosis as well as post-procedure TIMI-3I Flow as 86.7%. Going onto slide 78 we are now looking at the transfer costs. Hospital one had an average cost per transfer of about \$1,106 and these were transfers for emergent CABG. Transfer cost for hospital two which was other acute care hospital had an average cost per transfer of \$2,036. Slide 80, hospital three transferred to CABG facility cost per transfer is \$819. Slide 81, hospital four transfers for urgent CABG average cost for transfer was \$320.</p> <p>Dr. Ram – Slide number 82, hospital five transfer for urgent CABG average cost for transfer was \$2,190. Slide 83, hospital six transfer for emergent CABG and other acute care hospital average cost per transfer was \$916. That is the end of this section. I will give it back to Dr. Bommer.</p> <p>Dr. Bommer – Thank you very much. We are now on the home stretch for these slides here so if I can have you turn to slide 84. We are now going to talk about summarizing some of the information that we have gone through. Slide 84 is summary one slide. What you can see from that is that PCI CAMPOS has enrolled over 3,000 patients in the first 2-1/2 years of the program. Our hospital enrollment runs from a low of 97 up to a high of 390 PCIs per year. You can see we have a variability of basically 4:1 in our population enrollment among the PCI CAMPOS hospital sites. You can see the NCDR data that we have which is two years. There is 24 months of data that we used in this analysis comprises 99,000 patients so it's a large percentage we believe of all PCIs done in the State of California over those two years. Our pilot site audits detect more mis-codes with an odds ratio of 6.4 and mis-risk with an odds ratio of 14, than our central audits do in the PCI CAMPOS program. Our PCI CAMPOS STEMI incidents of 32.2% are significantly higher than the rest of California NCDR California STEMI rate of 17.7%. Our compassionate use in CAMPOS does change mortality from STEMI mortality of roughly 4.8% .it shoots it up to about 61.9% and this is really comparable to the other state that reports which is Massachusetts.</p> <p>Dr. Brindis – Might I suggest you parse that last bullet saying the compassionate use designation raises the mortality, otherwise it looks like something else is happening.</p> <p>Dr. Bommer – Got it, we will change the wording of that bullet. That's summary one slide. Slide 85 is summary two. In that we are talking about our risk model. As Dr. Li explained, we developed a relatively comprehensive multivariate logistic risk model. In the refined model there are 21 variables. The C-statistic is very high at 0.902. Using this model we developed or calculated risk adjusted overall composite events for a number of composite events of death or emergent CABG. There was no significant difference between PCI CAMPOS and California. The PCI CAMPOS risk adjusted overall event rate was 1.58% whereas California was higher at 2.11%. There is no statistical difference between those rates or numbers. For STEMI excluded</p>	
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composite events in the risk adjustment analysis there was, again, no significant difference with PCI CAMPOS at 1.15% and NCDR California at 1.16%, almost identical in that population if we excluded the STEMI population in the analysis. If we look at risk adjusted overall composite event outliers in the population we see that in the six CAMPOS hospitals we identified one outlier that was better than expected performance. There were no worse outliers in the overall composite for PCI CAMPOS. For the 116 non-PCI CAMPOS hospitals – that is the NCDR California data set shown in orange – there were four hospitals which were again outliers and better than expected and there were seven outliers that were worse than expected in the California population for overall composite events – death plus emergent CABG. If we look at operators we can see there were 47 operators identified in PCI CAMPOS, one operator for overall composite events and the overall population was better than expected. If we look at risk adjusted STEMI excluded composite event outliers we can see that for the six PCI CAMPOS hospitals they were all as expected and no outliers. For the 116 NCDR California hospitals there were four hospitals that were better than expected and five hospitals that were worse than expected as outliers. For the operators for STEMI excluded composite events we could look only at the operators from PCI CAMPOS. We identified no outliers for STEMI excluded patients for that. In turning to slide 86 summary three, you can see that the PCI CAMPOS success rate for the first two years showed a post-procedure residual stenosis rate less than 20% of 89.7%. The post-procedure TIMI-3 Flow – meaning good brisk flow in the coronary – was seen in 93% of the patients. So again fairly high success rates in the patient for post-procedure stenosis and TIMI-3 Flow. For NCDR and PCI CAMPOS hospital volume to performance correlation, we saw no significant difference in either NCDR or PCI CAMPOS between the hospital volume of number of procedures and the outcome as judged by the composite event rate, no statistical difference for that. Now, realize that we are not able to track PCI operators who do it at other hospitals. The last thing for quality metrics for PCI CAMPOS, we look at the quality metrics which are not performance metrics but listed as quality metrics for which we do not currently have risk adjustment. We can see that we are comparable with the rest of the U.S. NCDR data set. We do similarly for aspirin, thienopyridines which we'll interpret as dual antiplatelet therapy, stress testing, emergent CABG, door to balloon time, kidney injury, stroke, composite events which in this category is stroke, CABG, and death, length of stay, pre and post creatinine were all within the 25-75th percentile of the NCDR U.S. Data set. We found that for lipid medicines we were higher than the 25-75th percentile. For transfusions were below the 25-75th percentile but we were still within the 10-90th percentile of the NCDR National Data. For post-procedure biomarker we were somewhat outside of the 10-90th percentile for that meaning a little higher MI rate than the 10-90th percentile of National Data. That completes the summary. We are now on slide 87 and this just rehearses some of the information you heard over the last two meetings of obtaining the NCDR Data. We signed the contract, got the data, and we want to thank everyone on the AOC for voting to give us that NCDR data because I believe that was pivotal to having accurate analysis in comparison for PCI CAMPOS. We received all of that data, the complete data set, on 12/13/12 and it was turned around in a very short period of time over the holidays to in fact sort through 25 million data fields to do that. Slide 88 shows some of the plans we had at the last meeting in our follow-up. One of the concerns that we had was hospital volume. If you look at the numbers on our first graphs you can see that the volume has come down in the last six months in the PCI CAMPOS project. Our volumes are lower. We should hopefully still get 1,200 cases this year but it is going to be a push to get to the full 1,200 cases. We have surveyed operators as to why volume is down. The reasons are basically, well it's the economy, that was down. The other is that perhaps there are more selective cases to reduce mortality or to keep the outcomes looking good so we believe there may be some patient selection that has contributed to lower patient volume.

Dr. Brindis – It also reflects a national trend and better use of primary and secondary measures, adjunctive therapies.

Dr. Bommer – Number two is review performance variation. You remember at the last meeting we had identified two worse operators in our PCI-CAMPOS program with composite event rates

of 12 and 30%. We went back and notified the PIs in each of those cases. They reviewed the cases, looked at it and I am happy to report that in the year 2012 both of these operators had zero mortality for no composite events in that case despite performing 35 and 14 procedures respectively. Our variation has been eliminated and as you can see from our data we now have no outliers and everyone is as expected right now. Number three, refer outliers to local CQI. We notified our PIs and they were reviewed. They have gotten back to us with reports on some of those deaths or complications that were identified there. We believe that the CQI reports have been received by us now and they have been reviewed. We will also include reviewing CQI minutes when we are at our pilot hospitals doing our onsite visit just to confirm that there is an active process of CQI in each hospital that has been developed and implemented. We would like to reconsider the possibility of public disclosure. We addressed it at one or two of these meetings before. Currently we do not list the name of the hospital. We say hospitals 1 through 6. At some point it may be advantageous when this report goes to the legislature to actually list the name of those hospitals. We believe now that we have NCDR risk adjusted data which is extremely accurate and we are now countable enough that we can potentially review or release those names publically in our future reports. We would like to introduce that as a possible motion to be discussed later when I close my data set. We want to obviously obtain the data set from NCDR for December 2013 and we are very comfortable with it now in the last month. We would like to go through early publications that we have completed and outline some of the topics we want to discuss in perhaps multiple publications and we are in the process of preparing some of that material. We would like to discuss the PCI-CAMPOS transition plan. As you know, Senate Bill 891 suggests that we stop enrolling patients after August 1st of this year, 2013. We realize that about one year ago it was noted that in fact potentially hospitals would have to ramp from a high volume down to zero for a period of time until a decision was made by the legislature as to whether they were or were not going to approve offsite hospitals in the State of California. To get through that extension period we have suggested that SB 891 be extended. We have in fact worked on that. We have written several drafts of the extension language that currently are out there. We met with the California Hospital Association. They agreed to sponsor the bill, that is the extension bill for SB 891. We met with other groups and received support from (1) all of the pilot hospitals who have written me a letter stating they support the extension, (2) California American College of Cardiology, (3) California Medical Association, and (4) The California Nurse Practitioner Representatives. They have all agreed that they would support this extension bill. The re-written drafts are intended to be submitted prior to February 23, 2013 next month with that. They have been shown to the original author of the bill and that author is now reviewing it to decide if they will approve the extension under their name. If that author were to decline the extension we have other legislators who are available who could also author that bill at that time and submit it under their name. The submission will be prior to February 23, 2013. Slide number 89 is our analysis plans. As was brought up today, there are multiple ways of looking at this now complete data set of all California and PCI-CAMPOS. Not just for our primary outcome mortality and emergency CABG but all of these other variables that are there as well for which we could potentially risk adjust on each of those based on the data set we have. We are exploring publications that would deal with demographics episode of care, history and risk factors, cath lab visit, diagnostic cath and anatomy, the procedure, the lesions, the labs, the discharge medicines, outcomes, etc. There is a whole lot of things that we are in the process of exploring for that, it is just a matter of time. Our PCI-CAMPOS plans at this point are to submit Senate Bill 891 extension prior to February 23, 2013. As I announced, we will also be auditing the CQI records when we are at the remote pilot hospitals. Not to bring them back or take them out of the hospital because we understand their CQI but just for our reviewers to confirm that they see minutes from those meetings, that those particular events or mortalities were discussed in CQI, and that there is an active process at each pilot hospital. For mis-codes and mis-risks we are continuing to work with Velos at this point in time. That is a much larger data set then anything I have presented so far. We are in the process of trying to accommodate those, what we think would be something like, 50 million pieces of data that would be in that data set and how to effectively analyze that. We would like to consider comparing our NCDR robust critical data set with the PDD data that we had earlier to confirm that we are not missing any deaths or anything else. Also, to look at the comparison between the registry data NCDR and the PDD data for all California hospitals. We

<p>want to submit our two-year data for publication realizing that we could begin doing that this year. Lastly, we want to schedule our next AOC meeting before we leave here. With that, this concludes my presentation. I apologize for taking eight minutes longer this morning but we would be happy to answer any questions. I believe lunch is here. It is up to Dr. Way as to how long of a break we want to take for lunch. If you want I would be happy to work through lunch if people want to do that and consider an early exit from today's meeting.</p> <p>Dr. Way – Thank you. I would just like to ask to see if the members of the committee that are on the phone are still with us or not. I think that was Dr. French (here), Dr. Davidson (no answer).</p> <p>Dr. Sundrani – I just joined about 20 minutes ago, I apologize.</p> <p>Dr. Way – Okay.</p> <p>Dr. Jain – I am still here.</p> <p>Dr. Way – The reason I am asking is that last time we wound up with no quorum and we could not do any business at the end of the meeting. I also would like to take a lunch break. I think if we could take 15 minutes. This would allow people to either go downstairs if they are here on site there is a cafeteria that does food to go. Go out the front door to the left and they are in the building. Then we can maybe restart in 15 minutes which would be, by my watch, about 5 minutes to 1:00. If that is satisfactory with everybody then I think we will do that. I would also like to remind you that we have to pick the date of the next AOC meeting and because we did not have enough people here at the end, the date we set did not work or something. We will start up again in 15 minutes.</p> <p>12:24:LUNCH BREAK</p> <p>12:41:</p> <p>Dr. Bommer – Okay, I think we will complete the lunch break at this point in time and move on to the next item so we can get everybody out early this time. We now have completed the lunch break. To be honest, we did not have public comment about the data analysis so I think this would be a good time to open up. Is there any public comment about the PCI-CAMPOS data analysis? The data analysis is open for public comment at this time for the next several minutes.</p> <p>Dr. Brindis – I would like to make a comment and congratulate Bill Bommer and his crew at UC Davis for the incredible thorough erudite analysis and continual support of the AOS program. I also congratulate the foresight of your recommendation to obtain the NCDR data and the AOS Advisory Group concurring and voting and the hospitals supporting the purchase as such because the data analysis is becoming increasingly robust. I think that the services that you offered and the analytical results that you are putting forward really helps the State of California to have great oversight in terms of assessing the strategy of elective PCI without on-site surgical backup. So again, congratulations.</p> <p>Dr. Way – And as the only member of the state here that is directly responsible for this I would also like to thank you for your efforts and the UC Davis group, thank you.</p> <p>Dr. Bommer – Thank you very much. We will take any other positive public comments at this time.</p> <p>Dr. Bommer – If there are no further public comments then we will close that part of the discussion. Thank you and thank you all, to the AOC and all the members who are listening today for your involvement and your participation as well.</p> <p>Dr. Brindis – I am on a roll so I would like to make one more comment. You know, the State of California through the Figueroa Bill has public reporting related to coronary artery bypass surgery</p>	
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and my personal opinion is that it has improved care related to our cardiovascular surgery patients in the state. Actually even expanding things that we report on where initially we were charged to report an isolated CABG but we have looked at some process measures which have led to quality improvement for the patient to this date. I think the work that has been done here really shows nicely. If the state decides at some point to enter the public reporting arena related to PCI that we may have through your work and diligence have set up the infrastructure where the public, the state and more importantly our patients and our participating hospitals and physicians could feel comfortable with such data, so I wanted to make that statement.

Dr. French – Bill I wanted to congratulate you on a great effort. I think you have gone beyond the expectations here and have really done a great job at helping us understand. Congratulations.

Dr. Bommer – Thank you very much. As long as we are in the public comment I know that Ralph mentioned something about public disclosure. We have discussed it before. Currently there are four states in the United States right now that have public disclosure on PCI outcomes, Pennsylvania, New Jersey, New York and Massachusetts. The potential, I think, in the future is that California might consider that. My belief would be within the next decade California will be public reporting. I think it is a matter of time before the community and the public wants that information and requests it. We are not going to talk about state public reporting right now but one issue that I had alluded to in my slides was whether we want to consider PCI-CAMPOS public reporting. Now, what I mean by that is that not operators but hospitals would be willing to release their name to the current reports that we have. Instead of listing hospital one through six we would list their names. That is, public reporting for the purposes of PCI. There are some reasons for that. It allows a little bit clearer review of the data if we do not have to mask the hospital name and check it each time. Also, I think when the report eventually goes to the CDPH and then it gets forwarded to the legislature there might be more impact if they knew that there was an identity to each of these hospitals rather than being hidden at this point in time. So, I see advantages for that and I wanted to bring that up to the AOC in case the AOC wanted to consider that possibility. Then they would have to make a motion along those lines to literally de-mask the hospital names from the current data set.

Dr. French – I think that is a very good idea. I think the data looks very uniformed and very good. I do think that it would be an all or none.

Dr. Bommer – I agree, it has to be all or none. We are either publically disclosing the hospital identities for PCI-CAMPOS or not. It would be one way or the other. I would propose we only do this to hospital based and not operator based because operator numbers are not so high that we would have good statistical numbers on it. But for PCI-CAMPOS hospital numbers all of our hospitals now have big enough numbers and we have a very robust data set. Especially when we do risk adjustment using the over 100,000 PCI California data set.

Dr. French – It is our decision alone vs. the hospitals decision as well?

Dr. Bommer – Well, the protocol would be if the 12 members of the AOC made a vote or recommendation they would forward that to the California Department of Public Health. Then it would be CDPH who would review that with their legal people to make sure it was compatible and then CDPH would make the final decision.

Dr. Brindis – Bill's question is a good one. This group would have to decide whether we would want the hospitals themselves to have any input, or say or vote, in the process then you could post the motion as a recommendation to the state and the hospitals vs. the state alone. Is that a fair statement?

Dr. Bommer – Yes, the AOC is an advisory and I was just interested to see if the AOC as a group had a recommendation that they would either advocate for public disclosure in PCI-CAMPOS or not.

Dr. French – I would recommend that and I think that going forward then makes a lot of sense. I think other studies were under way and some facilities didn't do as well. I don't know if this would set a precedent for open disclosure for all future sites and that would make more hospitals hesitant to join. Having said that, I think transparency is better than a closed door and I would recommend that we go ahead with your recommendation to show the need for the six hospitals.

Dr. Bommer – Well technically since I am not an AOC voting member, my recommendation would have to be introduced as a possible motion by an AOC members.

Dr. Jain – What parameters would be reported? Do we have any understanding of that? Exactly what is going to be reported?

Dr. Bommer – A good question. Our current parameters are composite outcome that we have. We have the ability to look at additional outcomes. We have composite which is death and CABG. We have emergency CABG by itself and we have mortality by itself. The parameters that were presented today include additional outcomes. They include success rate, TIMI-3 Flow rate afterwards, and they do include an analysis that has some post PCI complications which have not been risk adjusted. Those include bleeding and hematoma which were listed there as well. There are 240+ variables in the system and yes to answer your question. If we announce that then we would have to define whether it would be released just for our primary outcome which is composite of death in CABG and restrict it to that primary outcome or whether we want to open it up for all outcomes and all data.

Dr. Sundrani – I am sorry I am late. There was an issue with connection here. I did not understand the basis. I did understand the comments of why, but I still don't understand what the basis is behind disclosing the names of the hospitals? That is my number one question for Dr. Bommer. The other part for me that is hard to understand is this bill gets extended and these are the six hospitals. If we disclose the names would this include any other hospitals who have not gone through this vigilance and all that stuff to be included? If that is the necessity of the area or would this be restricted to these hospitals? I just do not know where the topic is going from there.

Dr. Bommer – Okay, so to answer the two questions. I will take the second one first. That is, the extension process that we have written the language for does not include any other pilot hospitals other than the six that are currently enrolled in the system. We do not envision incorporating additional hospitals that are currently not participating. For the transparency and the public disclosure, as I mentioned there are four states in the U.S., Pennsylvania, New Jersey, Massachusetts and New York that because of public transparency currently publicly report PCI hospital outcomes at this time. We would just be joining those. What is the reason for it? Well we would have to ask each of those states what their reasons were, but primarily it is because of consumer or patient request to have this information available before they go in for a procedure.

Dr. Sundrani – In listening to your two answers, I think transparency is important. I think the data, like a bleeding issue, it is not risk adjusted. We have some issues in our data analysis too so I think my vote would be for transparency. I heard Dr. Fehrenbacher and I would say we just report the primary data outcome data.

Dr. Fehrenbacher – In the CMS when they report hospital data they do not report 240 variables. They report typically risk adjustment in mortality which is appropriate for consumers. Not just reading but looking at percentage biomarkers obtained post-procedure and then your cause and biomarker rate consistent with myocardial infarction post-procedure is extremely confusing for doctors, let alone cardiologists and could never be figured out by the public. The question is whether some of that data that is confusing, which is really more related to either the risk of the patient or simply whether the post-procedural laboratory value is drawn, I wonder whether or not that should be reported?

Dr. Jain – I think I agree with Dr. Fehrenbacher. There are a lot of variations in the patient population and just to report without adjustment I think is an issue. If everything is risk adjusted and reported properly then the public will be able to understand what we are saying. But, if we just publish absolute numbers and they do not make sense then I think that would not be fair.

Dr. Brindis – I would suggest if we were going to go down this pathway that any measure that becomes publically reported get vetted with a committee with a presentation as to its logic, its voracity, its risk adjusted aspects and whatever with the overall goal of promoting quality in addition to transparency, but not to confuse the public. If I was one of the six hospitals, if I was in the C suite, as opposed to being sitting around the table, the right question would be asked: If we are going to have public reporting of my hospital or my six hospitals why should we not have public reporting of all the hospitals. So, Dr. Bommer for example said we would be joining four states that have public reporting. Well, that is not true. We would be reporting our pilot study publically and blinding all the other hospitals in the state. So, for example Pennsylvania has a pilot elective PCI program but they have public reporting. I will assume that those hospitals are reported side by side with the others. Am I correct on that? So, I will ask that question to the group and some of their thoughts there.

Dr. Karmarkar – A couple of comments. If we go down the path of public reporting, (1) I think we should stick to key elements, few elements that patients can understand, a common person can understand. (2) I understand that we may not be able to get buy-in from all the other 116 hospitals to allow public reporting but if the six pilot hospitals do report it should be compared against . . . This is accumulative data for the rest of the State of California so patients have something to compare to, not just in isolation. (3) As we look ahead in changing the regulatory aspects of SB 891 and making it allowable for other hospitals to be able to do the PCI, I think it will be important to have a personal connection for those who pass the bills when they have the names of the hospitals, not just identify the hospital number, 1, 2, 3, 4, 5, 6 to a common legislature. It may not mean anything. What is hospital number one? They hear a hospital, or this is the Sutter Hospital, this is the Kaiser Hospital, etc. It personifies it and I think they will feel a personal connection through someone. There is a greater chance of looking at it positively rather than just a hospital number.

Dr. Brindis – One question I have to the six hospitals is that presently STEMI destination programs in different counties tend to be overseen by EMS services. My involvement with a number of counties in this state, and also sitting on the California STEMI program, was that one of the components of those county programs typically was a quality component where the hospitals participating as being a STEMI destination center would be sharing their data relatively blinded as a way of giving quality oversight to help EMS services and the hospitals. The question that I have to that long-winded introduction is – Is the data right now of our six hospitals being shared at a county level as you are participating in STEMI destination programs because it is all about quality in addition to transparency?

Dr. Fehrenbacher – The answer is yes, on a quarterly basis.

Dr. French – I think the reason we want to release the data is first of all it's wanted by the state so it's public information, or at least it should be. Second of all, I think that this is the beginning of reporting for all PCI hospitals in the State of California and we need to start somewhere.

Dr. Sundrani – Dr. Brindis, Clovis does not have a destination center assignment in spite of all the efforts of mine, Dr. Bommer and our hospital. The SDs we get, and we get quite a few of them, they just show up to our door without warning from the ambulance as an SD coming to your door. We are in a tough situation here with all of our efforts to talk to the EMS. They have that data so I do not know if we go public they would make us a destination center. They're actually flying by the hospital and going to the other area where of course I am the interventionalist in the other hospital. It is an interesting mix of situations here for us at Clovis.

<p>Dr. Forman – The last meetings that we have had here at the PCI-CAMPOS that information has been put out in public site correct? So the slides you show here as well are put out in the public right?</p> <p>Dr. Bommer – That is correct.</p> <p>Dr. Forman – So at least the names of these hospitals people could compare, well Kaiser Permanente site is number X. Back to where you were saying you shouldn't release all this data that shows maybe positive biomarkers and things of that order are now going to be relevant to the public because that data is already out there.</p> <p>Dr. Bommer – That was brought up by Ralph, or implied, and that is the question that we have. In other words, we would have to mask the data. If we just picked mortality, picked one performance measure that we have enough numbers that we feel confident with, we would have to report that in a way that could not be tracked back as an identifier to the current data sets that went out on the prior slide sets. When we reported over all, let's say mortality for a hospital, it would have to be a little bit different time zone previously reported and it would not contain the volume so that you could break the code and find out which hospital had that volume. We would be careful with that. What I would propose if we went that step, we would prepare a template of what we are going to do and then present that to the AOC board to make sure they felt comfortable, still protective enough and only dealing with performance, risk adjusted material that we felt comfortable with releasing.</p> <p>Dr. Fehrenbacher – I believe that the data could be placed on the website that did not indicate the numbers and therefore you could not look back. There would be a way to do that.</p> <p>Dr. Way – Right now after this meeting this presentation will go on the CDPH website so whatever is here is what you can get if they want it. I don't know how many people ever look at it.</p> <p>Dr. Karmarkar – Another option would be to leave the presentation in terms of the identified hospitals, hospital 1, 2, 3, 4, 5, 6, but make a separate slide in the part of the summary that would need separated captures, in essence, of what the AOC recommends. We want this data disclosed and the disclosure might be the six pilot hospitals are And their mortality or event rate or CABG rate or whatever is comparable to NCDR data set or something like that.</p> <p>Dr. Brindis – The public reporting mechanisms to get it out would probably be in a different type of venue also. You would come up with a modest report in how it is actually presented to the public. This is transparent but it is nothing like everybody is going to pick up the morning newspaper and read about it in general.</p> <p>Dr. Fehrenbacher – I am less concerned about a computer sleuth who is really into this data and is smart enough to trace back and use our work load to do that . . . If that person wants to do that then that is okay with me. It is simply publishing all the data so that someone can easily look at, and get confused as well.</p> <p>Audience Member – I am not really sure who has the authority over this. My concern is if it becomes published from the state that means it goes through lots of review processes and it's a huge delay. It's just something to think about. If there is a way you can put it out there through the UC Davis team that would probably be preferred.</p> <p>Dr. Bommer – Well, I believe that the authorization here is that the AOC makes recommendations. Those recommendations are then given to CDPH and CDPH is the regulatory agency that was authorized by the legislation to develop this program. CDPH is the authority at this point for any actions that we would take.</p> <p>Dr. Way – But we are working off the senate bill and there is nothing in the senate bill that is</p>	
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<p>interested in de-identifying information or identifying information so this is something new. I would be happy to receive it but I would not know what to do with it.</p> <p>Dr. Fehrenbacher – I might suggest just simply on the website the risk adjusted mortality for each hospital is identified and that is it, to start off with. Then maybe next meeting we can re-discuss it but it would seem this would be simple and straight forward.</p> <p>Dr. Way – Well, make sure that before you put anything on the website that identifies any facility in this study I have to go through legal.</p> <p>Dr. Brindis – Our general model in CABG is the hospitals have an opportunity to look over the data, it should be a transparent process to the hospitals themselves.</p> <p>Dr. Karmarkar – I was going to suggest that we can make a recommendation yes or no. Even if it's no I think we represent yes the hospitals but we are affiliated with those hospitals and I think we need to get an okay from the hospitals themselves to have that data out for them.</p> <p>Dr. Brindis – So the best way would be for each individual PI to contact their CEO or whoever else represents the hospital and to do that footwork themselves.</p> <p>Dr. Karmarkar – I am suggesting we can have a vote here. Let's say it is approved that we don't mind having the data made public, or parts of it, as we discussed earlier, then we take it to CDPH and their legal counsel. They say this is fine then from CDPH let us go to the hospital CEOs and say is this okay? Is that too convoluted?</p> <p>Dr. Way – I think you have to come to us with what you want. We're not going to go out and ask the hospitals anything. We're regulated. We don't ask hospitals what they want.</p> <p>Dr. Fehrenbacher – Go to your hospital and find out if it's okay with your hospital. Then email Dr. Bommer. Then Dr. Bommer can give the information to CDPH and see if CDPH can then run it through legal and then you're done.</p> <p>Dr. Sundrani – I think we should have a vote on this that has been discussing here for the last 15 minutes or so about what the members are feeling. Whether we should transfer it and report it. What I am hearing is an agreement but I think we should have a vote and then go talk to the CEO and whatever you decide then go from there but we should vote.</p> <p>Dr. Bommer – I agree, I think we can entertain a motion right now from one of the AOC members to consider publishing the name for limited data set which I think would include only mortality at this point. Since we have so few emergency CABGs I would suggest to keep it simple. We do mortality only and we have a simple release; hospital name and risk adjusted overall mortality. Now, if you would like we could also include STEMI excluded risk adjusted mortality as well because, as you know, both of those numbers reflect slightly different populations. The STEMI excluded mortality is lower, it's half the rate. Because we have so many our mortality from STEMI is about 2% for the group but our risk adjusted mortality for STEMI excluded is 1.15%. So I would say list the hospital name, total mortality and then STEMI excluded mortality for the hospital and that is the limit of the public disclosure that is associated with a name of a hospital.</p> <p>Dr. Fehrenbacher – I am going to make that motion and that each AOC hospital PI goes back to their hospital and gets approval from their hospital for that.</p> <p>Dr. Forman – If you are planning on doing it that way can the data to be released be opposite of the NCDR numbers right next to it or is it just going to be a random? If I am the patient and I just go look and I see Sutter Hospital has a 2.5% mortality rate what does that mean to me? Is that good or is that bad?</p>	
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<p>Dr. Bommer – We can release in addition to that the NCDR California number next to it and we can have “p” equals nonsignificant for the relationship if you want to go to that level.</p> <p>Dr. Forman – I think most people won’t understand that but you would be obligated to do that.</p> <p>Dr. Fehrenbacher – You could say no difference.</p> <p>Dr. Bommer – Yes, we would say no difference. And if you look at the numbers they are very close.</p> <p>Dr. Karmarkar – I second the motion.</p> <p>Dr. Sundrani – So we are deciding on publishing the risk adjusted mortality rate and risk adjusted event rate?</p> <p>Dr. Way – Fehrenbacher made the motion.</p> <p>Dr. Brindis – I am not sure what the motion is. One motion talked about talking to your hospitals first and another motion talked about presenting this to the state. Those are two very different things. I might anticipate the answer might be different. We may come back to another meeting to report back on your hospital.</p> <p>Dr. Fehrenbacher – Would you agree that both need to be done?</p> <p>Dr. Brindis – Absolutely, that is my assessment.</p> <p>Dr. Fehrenbacher – So the motion was a complex one and it suggested that the risk adjusted mortality for each individual hospital be identified and compared with the NCDR average of California with or without STEMI and each PI will obtain approval from their hospital for that to be published. After approval from all six hospitals have been obtained that would be submitted to CDPH for legal review and publication.</p> <p>Dr. Bommer – So that was a restated motion. That would need a second if it goes.</p> <p>Dr. Karmarkar – I second the motion.</p> <p>Dr. Forman – When are we going to come back with this information from the hospitals?</p> <p>Dr. Bommer – So this motion is now open for discussion.</p> <p>Dr. Forman – I know the motion is to go to the hospital and find out what they want but how is that then going to be related back? Are we going to do that the next meeting?</p> <p>Dr. Fehrenbacher – Email Dr. Bommer.</p> <p>Dr. Forman – Okay.</p> <p>Dr. Way – I have not been participating in this because I don’t think this is really part of the committee that I am here to represent.</p> <p>Dr. Bommer – As far as the discussion is concerned, I would not move or send that data to Dr. Way for evaluation until we have all six. In other words, unless it is unanimous I would not proceed. I would want a letter in writing from each of the hospitals saying this is our position.</p> <p>Dr. Brindis – In all honesty, I think we need to have something in writing as to what was actually going to be made public. So we need to parse out fully the brilliant motion by George so they</p>	
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<p>actually can see in writing. They are going to run it by their legal people so we need to have that all parsed out.</p> <p>Dr. Jain – Is it possible to see the risk adjusted mortality rate of each hospital individually?</p> <p>Dr. Bommer – Yes.</p> <p>Dr. Fehrenbacher – Do you know your hospital number?</p> <p>Dr. Jain – Yes.</p> <p>Dr. Fehrenbacher – Then you know it.</p> <p>Dr. Jain – But I don't think we saw each hospital individually, did we?</p> <p>Dr. Fehrenbacher – Yes but they were not identified.</p> <p>Dr. Brindis – Actually you told us what your hospital is. We know your risk adjusted mortality.</p> <p>Dr. Bommer – I think you probably know what your hospital numbers are, what your deaths are, but we can give you the risk adjusted for each specific hospital. I can send that out to you.</p> <p>Dr. Jain – Yes, if you can have that I would really appreciate that.</p> <p>Dr. Bommer – It's not individual risk adjusted, it was the pool of six hospitals.</p> <p>Dr. Jain – I would like the individual hospitals.</p> <p>Dr. Bommer – We looked at it because they were all as expected and no outliers with the single exception that one hospital was a better performer.</p> <p>Dr. Brindis – And one operator.</p> <p>Dr. Bommer – And one operator but we are not discussing operators at all on this motion.</p> <p>Dr. Jain – I don't think we saw individual hospitals.</p> <p>Dr. Bommer – No but we can provide you with that data. I can tell you that all six hospitals were as expected meaning that they were no outliers for the mortality that we are talking about.</p> <p>Dr. Brindis – Dr. Jain's point is actually a good one because the CEO . . . The public does not understand statistics and will see one number and how people look at it is different.</p> <p>Dr. Jain – I appreciate it, thank you.</p> <p>Dr. Bommer – So I believe there is a motion on the floor. It was seconded. It was discussed and now there is the possibility that you could call the motion.</p> <p>Dr. Fehrenbacher – One more point of contention, Dr. Bommer you will email us the individual numbers so we can present the slide that will be presented publically and so we can present that to our CEO is that correct?</p> <p>Dr. Bommer – Am I allowed to do that?</p> <p>Dr. Way – As I said I am not participating in this, but you guys can do whatever you would like.</p>	
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<p>Dr. Bommer – In other words, does that interfere with Bagley-Keene that I am sending information to them without making it publically disclosed.</p> <p>Dr. Way – I think its part of the data that you presented, it's just that you are going to identify it.</p> <p>Dr. Li – We have deaths or emergent CABG as composite. If you want just random for patient mortality everything will be changed. So mortality risk model will be changed.</p> <p>Dr. Fehrenbacher – Why we can't just use the data that was presented to us, the composite?</p> <p>Dr. Li – That is no problem.</p> <p>Dr. Fehrenbacher – Even through CABG was quite rare, it's so rare that it does not really make much of a difference.</p> <p>Dr. Bommer – You tell me the outcome and whether it's all cases. Because they are different I would suggest that the two numbers we report would be for all comers or all cases and the other would be for STEMI excluded. I would suggest those are the two reporting numbers. Then we identify each of the hospitals and only for that data and we give you the number for your individual hospital. We will email each of the PIs with the number for their hospital for the first two years.</p> <p>Dr. Brindis – In the email will you put it in writing to help empower and enable the PI to have something in writing to go forward to the CEO of the hospital?</p> <p>Dr. Bommer – I am not sure what the correct empowering language would be?</p> <p>Dr. Brindis – Actually it would be emasculated, they won't be empowered. The first thing they are going to say is show me what is actually going to be done.</p> <p>Dr. Bommer – We will have a template of this is what would be released. There will be five blanks and one filled out because we can't divulge the other hospitals to your hospital until everybody signs on board. We cannot show you the final form of it but we will show you what the slots would be for those two numbers for your hospital. It was also proposed that we report NCDR California numbers along with those so we would have California NCDR data set for total PCI mortality and STEMI excluded. Then we would have hospital number 1, 2, 3, 4, 5, 6 and if this gets approved all of that way, the motion passes and CDPH goes along with it, then that would be the final thing that would be published on one page.</p> <p>Dr. Way – I think for Bagley-Keene, you probably need to go ahead and collect the data and then we will have to present it if we are going to do anything with the state, present it at the next meeting. You can send it to me and I will get legal. I don't think we can do anything unless it's done in open meeting, the final discussion.</p> <p>Dr. Bommer – So we still currently have a motion on the table that was seconded. There was a call of the motion.</p> <p>Dr. Way – It's your process so go ahead.</p> <p>Dr. Bommer – So it would be a call for a vote of the AOC members if they want to continue.</p> <p>Dr. Way – All in favor and state your name.</p> <p>Dr. Brindis – Would it be reasonable to ask the motion be read at this time? I'm retired, I'm not a member of a hospital, and I'm just trying to help the hospitals here.</p>	
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<p>Dr. Forman – I think we need to make sure we have a quorum.</p> <p>Dr. Bommer – Let's start with a quorum first.</p> <p>Teresa Fleege – Dr. Arnold (here), Dr. Brindis (here), Dr. Davidson (here), Dr. Farsani (no answer), Dr. Fehrenbacher (here), Dr. Forman (here), Dr. French (here), Dr. Itchaporia (no answer), Dr. Jain (here), Dr. Karmarkar (here), Dr. Smith (no answer) and Dr. Sundrani (here)</p> <p>Dr. Way – So all in favor state your name.</p> <p>Teresa Fleege: In favor – Dr. Arnold (yes), Dr. Brindis (yes), Dr. Davidson (yes), Dr. Fehrenbacher (yes), Dr. Forman (yes), Dr. French (yes), Dr. Jain (yes), Dr. Karmarkar (yes), Dr. Sundrani (yes). So that is unanimous with nine votes.</p> <p>Dr. Way – So it is unanimous with nine votes.</p> <p>Dr. Bommer – The vote passes. I think that at this point we can proceed to the discussion of extending the PCI comment. This ends the public discussion for the data that we had. So it is extending the PCI data. This won't take long because I did present it a little bit on the slides. There is a question of how long the PCI-CAMPOS program will extend. Originally it was for three years and the end of the three-year enrollment period would be August 1, 2013. Technically that is the contract that the CDPH has with UC Davis which would end the audit and the data acquisition then and start preparing for the reporting to the legislature. Then it has been interpreted that the volume of PCIs would have to ramp down by either August 1st or by January 1, 2014 clearly to zero at that point in time. Then the process of generating the audits after the three-year data collection, which will take at least three months and then processing of the data is another three months after that. Then the report goes to the legislature. We don't know how long it would take the legislature to actually look at that. They then have to make a motion, get sponsors of either approval or denial of this program in the future, go through committee and that could take literally 3 to 6 months in the legislature to get approved. There is a hiatus where the current hospitals that are doing PCI would have to clearly ramp down to practically none or zero PCI cases, certainly no elective PCI cases at that time. So if perhaps the program is approved to continue in the future there is a gap. They would have to stop for a period of time and then restart to try and assume those volumes again later. That gap has been proposed that we fill it with an extension of SB 891. That extension is anywhere from 6 to 18 months. It simply just extends the approval of the PCI-CAMPOS program until the legislature gets the report and makes their final decision as to whether PCI in California at hospitals without on-site surgery will be allowed to participate in the future or not. The extension clearly is just an SB 891 extension. It would only authorize current hospitals in the program to continue. There would be no additional hospitals added or subtracted to the program. That process has received some support. As I said earlier, we have talked with the original author. We have received a sponsor that is from the California Hospital Association. A sponsor is absolutely required to get this amendment passed but we do have a willing sponsor. We have written the draft language for that extension. I met with the California Medical Association and the California American College of Cardiology and they have approved it by board vote. I have met with Nurse Practitioners as well. So we have general support for this and I have support from the CEO of each of the pilot hospitals in a letter of writing saying that they would support this at this time. There is a process ongoing now to submit this extension bill language to the current legislature before February 23, 2013. It would then go to committee and the committee then, if it passed, would then go out to the assembly and to the senate for passage at that time. If they passed this it would only authorize continuing enrollment of patients until the legislature made their final decision as to whether a go or no go on the program.</p> <p>Dr. Way – Does somebody want to make a motion?</p> <p>Dr. Bommer – I do not believe we need a motion at this point in time because this is actually</p>	
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<p>happening outside of the AOC and outside of the CDPH, but it is open for discussion if anyone has questions or wants to add comments.</p> <p>Dr. French – What if you submitted this report as a semi-final report while you still collect data? The 3,000 patients is a pretty robust number. Chances are another 1,000 patients aren't going to change too much but this could be looked at by the legislature now in the next 3 to 6 months.</p> <p>Dr. Bommer – Well, because what we presented today is public information what I intend to do is include that presentation to both the author of the bill, the healthcare committee that reviews it, as well as make it available to the senate and the assembly for their votes. So yes, this information will be disseminated. The current bill SB 891, however, does not allow for an early reporting at two years. It requires three years so to change that we would have to amend the bill anyway. No matter how we walk around this we unfortunately have to make a change in the current SB 891 through language that has been written up to encompass not only that initial reporting that we are talking about now but final reporting and the decision by the legislature at that time.</p> <p>Dr. French – What are the cost implications of an extension?</p> <p>Dr. Bommer – The cost is relative to whether we continue with monitoring and auditing and report generation. The six hospitals, the CEOs, the sponsor of the California Hospital Association and CHA said they do not want to change anything other than just extending the current study which is at the current level of cost for that. Each CEO of the six pilot hospitals has said they would continue to contribute to the cost at their current rate to support extending the program. So, yes there is an additional cost of continuing and that is related to the audit process. Each of the pilot hospitals has said they would do that and continue to contribute and had no objections to that.</p> <p>Dr. French – Okay, thank you.</p> <p>Dr. Karmarkar – Can the processes occur in parallel? In other words, we ask for extension and there are a greater chance that it is passed or accepted and at the same time start working with the legislature, saying “Hey this is the study, so far the data looks excellent, we don’t anticipate much change in the way the data looks.” Can we get them prepared and give them a heads up that this is coming so the final passage and changes in the wording of the law will occur sooner than later?</p> <p>Dr. Bommer – The answer to that is yes. In other words, we have data now that will be prepared that can go in. At any point, including tomorrow, the legislature could introduce a new bill that totally authorizes this for the rest of the state and ends the transition period as well. In talking to the legislatures and the sponsor, California Hospital Association, they did not feel comfortable making that decision at this time. They want the study to go through the full three years, the data analysis to continue, and they do not want to introduce a bill that would have a premature decision. We do not have a sponsor or an author for that premise but we would make that information available should someone want to introduce that bill early.</p> <p>Dr. Arnold – Also, just the act of going through that extension sensitizes the legislature to what the data is going to be. It would be an education process.</p> <p>Dr. Forman – You had said 6 months or 18 months as far as the extension.</p> <p>Dr. Bommer – It comes down to the fact that in one of the contracts between UC Davis and CDPH it ends enrollment on August 1, 2013. So technically we would be extending enrollment for a period of time. The best number to put on that is until the report was received by the legislature and the legislature made their final decision. That is the best timing of that. Who knows how long it will take for a replacement bill that authorizes this in other hospitals throughout California to make its way through the legislature. We initially proposed a minimum of 6 to 18 months, but in reality the best language that we have set out right now is “or until the legislature</p>	
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makes their decision.”

Dr. Brindis – How do you budget for that? I assume you have to come up with a budget that you are going to offer the state and the hospitals then have to pay which of course they are going to want to do that because they don’t want to . . . How are you going deal with that?

Dr. Bommer – We’re not going to work on budget until we get an extension passed. If the extension SB 891 does not pass there will be no need for a budget.

Dr. Fehrenbacher – We all have an invested interest in this. Certainly, if it does not look like it's going to pass, or if there is some sort of blockade somewhere then we need to be notified early. Not after it gets voted down by the sub-committee or likely to be voted down in the legislature itself. It is more likely to be blocked at a committee level. We need to know ahead of time so we can do whatever political tricks we might have to try and help that get through.

Dr. Bommer – So I would propose that (1) I notify you when the bill is submitted, (2) We notify you when it’s in committee because if it’s in committee we will try to provide you with the names of the committee members should you want to provide input to those committee members, and (3) We will notify you when it gets out of committee and goes out on the floor of that senate in the house. At that point, you may want to contact legislatures from your district, or ones that you have a personal relationship with, to give them your opinion as to whether that extension bill should be passed or not. Are there any other questions on the extension? It is officially open for public comment so let’s open it now. Are there any members of the public that would like to comment on that discussion? Hearing no public comment on that we are now onto the next item which is future meetings and to review dates for future meetings.

Dr. Way – Bill and I discussed at lunch that the data that you are collecting now for the next period of time won’t be done until probably October which was when we had our last meeting, and we had it for the same reason in order to get the data completed. To me, it does not make any sense to go through the process of giving this data for 3 or 4 months. We are almost at the end of this particular project and it would be better to just have the data presented in its close to finished product as possible, again in October. The process sunsets in August and we will need a month to process the data and make the slides and the statistical analysis. Realistically, October would be the earliest that we would be available.

Dr. Fehrenbacher – CDPH is going to be preparing a report to them?

Dr. Way – We have a contract with UC Davis, but the way I read the senate bill, which is different from the contract, is this had to end on January 1, 2014. Then we have three months (90 days) to get it to the legislature. We need all the time we can get but if the data that would complete this project is available in October...

Dr. Fehrenbacher – The way I read it is we have 90 days from August 1st

Dr. Way – No it says in there it sunsets on January 1, 2014 then within 90 days we have to present the data to the legislature to make a decision.

Dr. Fehrenbacher – But then what will happen is, there won’t be enough time.

Dr. Way – We don’t have to wait until January. We are going to start in October but we won’t have the data until October that we are going to be working on anyway.

Dr. Karmarkar – Okay, but what I would like to know come August 1, 2013 are we going to stop enrolling or will we assume that we can keep enrolling until we hear from you and what is the final word?

<p>Dr. Way – You are going to have to stop enrolling.</p> <p>Dr. Bommer – To answer that, that is exactly why the extension is currently in formulation. The reason is that if the extension gets passed (we intend to pass it as urgent) then it would take effect as soon as the vote was done and it was signed by Governor Brown. It would become effective immediately prior to August 1st so you would then not ramp down August 1st but continue through August 1st. We would lock the data up until August 1st. We would use that data. It takes us a week just to get the data entered into the website. Then when we get that we have to sit there and send out investigators. That takes at least a month to go down to each of the hospitals and review the data. Then we come back and we have the angiograms to review. That takes another month to go through 100s of angiograms and review them and get that data back to the site. You saw the PCI audit process. It is a very interactive process. There are already 15 steps in that. That literally takes three months before we can lock down data at the minimum after the last enrollment. That is three months. Then it is another month to two months to do the statistical analysis and do all of that processing because we have to match and do risk adjustment models and everything else at that time. So there is a process that takes place. We would currently expect the last lock down data patient would be enrolled on July 31, 2013. We would then lock down that data and begin processing it. We would have our report completed by December 31, 2013 and give it to CDPH at that point in time. CDPH will then have the opportunity to generate a report and within 90 days submit it at that point. But, that is dangerously close to the end of the year and the process and everything else thereby lies the rationale for the extension which would continue not just up to January 1st but for up to another year. So then, the extension language goes until January 1, 2015 or until the legislature makes their final decision.</p> <p>Dr. Fehrenbacher – The legislative cycle starts January 1st and if you start to write the bill and make the report January 1st you likely will not make such a groundbreaking bill in 2014 and you will wait another year. So I guess my sense of this is that it is better to have the report written simultaneously while we write the bill next fall. Have the bill ready to go, hand the report to the legislature January 1st, have the bill written on January 1st and then you submit the bill at that time. If you wait 2 or 3 more months then you get lost in the cycle and you don't get your place hold in the sub-committees. I believe that the extension will not have much argument against that. But there will be controversy surrounding a larger bill that encompasses more sites and that is going to be a more difficult political battle in my humble opinion?</p> <p>Dr. Way – Right now we are just talking about the date for the next meeting.</p> <p>Dr. Bommer – Well just let me read you the amended language in Senate Bill 891 extension. The pilot program may continue until such time as the legislature enacts legislation to permanently authorize or end the pilot. There is no specific date so we don't have to worry about that. If it looks like we're rushed then we can't do it.</p> <p>Dr. Way – That is what you have written, that is not in the current.</p> <p>Dr. Bommer – That is not in the current bill, that is in the language of the extension. That is the only way we can handle all of these contingencies. I agree with George, is that it takes time to get this stuff processed through legislature and six months to a year is a typical waiting time for these processes.</p> <p>Dr. Way – So with that said when are we going to have the next meeting?</p> <p>Dr. Bommer – I would propose that we have a meeting in October of this year whereby we would then have at least locked up or gotten close to locking up data from the first three years. We would not have our final report at that time but we could at least present to you what the mortality was and the composite outcomes were for the first three years at that point. That data would then go through further processing and we would try to get that in good shape to send that as a report to CDPH prior to December 31st. They would receive it prior to December 31st and then</p>	
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<p>CDPH would have up to 90 days to turn it around at that time. If the extension is passed it covers us for those time lines at that point for the six pilot hospitals. If you're another hospital out there that wants to jump in early, they would not get that same advantage.</p> <p>Dr. Fehrenbacher – I think with that time line it essentially guarantees that there will be no bill submitted in 2014 for a permanent solution to Title 22. That's what I would say. If that's what the committee accepts, that there won't be a permanent bill submitted in 2014 but that the permanent bill would be submitted in 2015, then that is what they accept. So it will be 2016 before the solution to Title 22 occurs.</p> <p>Dr. Brindis – Did we pick a date in October or do we do that today or how is that going to work?</p> <p>Dr. Way – I would like that done today. We traditionally have met on Thursdays I think. We have 3, 10, 17, 24 and 31.</p> <p>Dr. Fehrenbacher – I am suggesting that's the way it's going to fall if we do it that way. If that is what everybody is okay with I will be begrudgingly carried along.</p> <p>Dr. Way – Well do you have a different date that you would like to do this?</p> <p>Dr. Way – This is just for a meeting.</p> <p>Dr. Fehrenbacher – Right, I recognize that. I would suggest that the data get locked down earlier. The final data is presented some-time in September and then the AOC will need to meet and help the CDPH write its report. Likely CDPH will look to the AOC for some guidance I would hope – all 12 members to write its report – and at the same time a bill needs to be written that jives with the CDPH report next fall. If we were to submit this in 2014 that's the time line that I would choose.</p> <p>Dr. Way – The only reason I brought up October is I was trying to think of the logistics of UC Davis being able to actually have the product.</p> <p>Dr. Fehrenbacher – But if they have most of the data locked down except for one month's worth, than the gist of the outcome will be clear.</p> <p>Dr. Bommer – With George's proposal we could do that if the coders could guarantee to give us the data within 24 hours and on the queries to respond within 16 hours to our queries. There is no coder here who wants to . . .</p> <p>Dr. Brindis – George, no offense but I think you have to go with what the analytical center suggests is the right time frame for billing to present the analysis. You can in a parallel fashion start setting the seeds with a legislative report.</p> <p>Dr. Forman - What does the CDPH report have to say?</p> <p>Dr. Way – It is a recommendation to the senate about what to do.</p> <p>Dr. Forman – So is that a 50 page document or that's a five page document?</p> <p>Dr. Way – It could be one page. I have no idea how long it will be but it's just a document that either supports or does not support continuing this process and removing the restrictions entirely.</p> <p>Dr. Forman – So that document doesn't necessarily need to take 90 days to be formulated?</p> <p>Dr. Way – Well, it has to go through our processes. It's good if it comes to us. I have no experience in writing legislation but I think most of it is written by people that aren't legislators.</p>	
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<p>So it has to come to us in a way that will make sense, pass our legal department, make sense to me as the chief medical consultant, and I can assure Debbie Rogers that it is okay. She may want to send it out to some cardiologists to see what they say, so I would imagine it would take a month to get it through once it's given to us.</p> <p>Dr. Bommer – So this is what the report shall include based on SB 891. The report shall include but not be limited to an evaluation of the pilot program's cost, safety, quality of care. The report shall also include a comparison of elective PCI performed in connection with an elective PCI pilot program and elective PCI performed in hospitals with onsite cardiac surgery services. The report shall further recommend whether elective PCI without onsite cardiac surgery shall be continued in California and, if so, under what conditions.</p> <p>Dr. Fehrenbacher – My suspicion is that it's not going to be an all or none issue. Title 22 will not be repealed.</p> <p>Dr. Way – It just changes a little part of Title 22, four lines, that's all it's going to change.</p> <p>Dr. Fehrenbacher – It's not going to be completely repealed. I'm sure there will be provisos in there.</p> <p>Dr. Way – The only provisos that I would put in there would be the ones that we would put in for the people who became part of this project which was to have an equality of the investigators and the equality of the facility. I have no other issues.</p> <p>Dr. Bommer – There may also be a selection because. In this program we have selection criteria that we have looked at meaning the patients who are in the eyes of the investigator not likely to do well are not going to be done at off-site hospitals.</p> <p>Dr. Way – They would be a third party. It would be as succinct as possible, be understandable and would take effect as soon as the senate made an adjudication and chose to vote on it if they did so, assuming we are going to have good outcomes.</p> <p>Dr. Bommer – Operator selection, patient selection, hospital selection process.</p> <p>Dr. Brindis – So what day in October on Thursday should we meet?</p> <p>Dr. Way – We met last year on October 4th.</p> <p>Dr. Bommer – I would say we have the option of October 3, 10, 17, or 24. Those are the options. I don't want to give you too many options. We only have those days.</p> <p>Dr. Karmarkar – I cannot do the 10th so we can do 3, 17, or 24.</p> <p>Dr. Brindis – 3 or 17 would work for me.</p> <p>Dr. Bommer – How about 17 then?</p> <p>Dr. Davidson – I am sorry to interrupt. Thursday morning is the only day that I cannot generally make it. I have been in and out of this conference all morning. Is there a possibility we could do it on another day other than Thursday that would work for everybody?</p> <p>Dr. Bommer – Well, we can do it on Wednesday as far as I am concerned. You would need to do a poll. Wednesday the 16th, how about Wednesday the 16th, the middle of October?</p> <p>Dr. Way – Does it not work for anybody? Please speak now or forever . . .</p>	
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<p>Dr. Sundrani – We will have to make it work.</p> <p>Dr. Bommer – Wednesday, October 16, 2013.</p> <p>Dr. Way – What else is there? We have action items for future meetings, I think we covered that. It will be self-evident as we go.</p> <p>Dr. Bommer – I have it in my phone and we decided on a future meeting. I think it is now time to consider adjourning. We will open it again for public comment. Are there any additional public comment, or investigator, or hospital site comments? Hearing no comments we want to thank everyone for their participation. This is outstanding to have our entire forum throughout the whole day. We appreciate that, everybody changed their schedules and scurried around to do that we really appreciate it. We appreciate all of the hospitals participating and their efforts in running with this program and contributing to its current level of success. We want to thank everyone. We expect to see you October 16, 2013. Good luck in the new Mayan Calendar. Thank you.</p> <p>Dr. Way – We are going to sign off now, thank you very much.</p> <p>14:27 – Meeting Adjourned</p>	
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Acronyms

ACC	American College of Cardiology
AFL	All-Facilities Letter
AOC	Advisory Oversight Committee
AUC	Appropriate Use Criteria
AVI	Audio Video Interleave
CA	California
CABG	Coronary Artery Bypass Graft
CAMPOS	California Audit Monitored Pilot with Offsite Surgery
CDC	Centers for Disease Control and Prevention
DPH	California Department of Public Health
CMS	Centers for Medicare and Medicaid Services
CQI	Continuous quality improvement
CT surgery	Cardiothoracic surgery
EKG	Electrocardiogram
FFR	Fractional Flow Reserve
HIPAA	Federal Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MI	Myocardial Infarction
NCDR	National Cardiovascular Data Registry
Non-STEMI	Non-ST Elevation Myocardial Infarction
OLS	DPH Office of Legal Services
OSHPD	Office of Statewide Health Planning and Development
OR	Operating Room
PCI	Percutaneous Coronary Intervention
PDD	Patient Discharge Data
RCA	Right coronary artery
RAMR	Risk adjusted mortality rate
SCAI	Society for Cardiac Angiography and Interventions
STEMI	ST-Elevation Myocardial Infarction
STS	Society of Thoracic Surgeons
TIMI	Thrombolysis in Myocardial Infarction
UCD	University of California at Davis